THE FEDERAL ROLE IN INTERNATIONAL TESTING, CERTIFICATION AND QUALITY ASSURANCE

HEARING

BEFORE THE

SUBCOMMITTEE ON
SCIENCE, RESEARCH AND TECHNOLOGY

OF THE

COMMITTEE ON
SCIENCE, SPACE, AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

SECOND SESSION

JUNE 26, 1990

[No. 145]

Printed for the use of the
Committee on Science, Space, and Technology

U.S. GOVERNMENT PRINTING OFFICE
34-217 WASHINGTON : 1990

For sale by the Superintendent of Documents, Congressional Sales Office
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THE FEDERAL ROLE IN INTERNATIONAL TESTING, CERTIFICATION AND QUALITY ASSURANCE

TUESDAY, JUNE 26, 1990

House of Representatives,
Committee on Science, Space, and Technology,
Subcommittee on Science, Research and Technology,
Washington, D.C.

The subcommittee met, pursuant to call, at 9:35 a.m., in Room 2318, Rayburn House Office Building, Hon. Tim Valentine (chairman of the subcommittee) presiding.

Mr. Valentine. The subcommittee will come to order.

We are here today to complement our international standards hearings of last week by discussing the effectiveness of the United States' system for applying those standards.

I have a statement which I will complete after I have yielded to our colleague, who has other commitments and needs to make his appearance and move on. So I will recognize at this time the Honorable Norman Sisisky from the State of Virginia. He has a statement which will appear in the record as presented to us. I will ask him to proceed in any way he deems appropriate. We're happy to have you here, sir.

STATEMENT OF HON. NORMAN SISISKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF VIRGINIA

Mr. Sisisky. Thank you, Mr. Chairman. I appreciate your courtesy for allowing me to go. I told you what the problem was. I just wanted to reiterate that I'm delighted that you're having this hearing.

The ability of U.S. labs to test American products for the European market I think is at stake. I would hope that we would find a way to help U.S. products be more easily accepted in the European Community. We need to help our American labs achieve certification in the 1992 environment, and I will work with you in any way I can. I am Chairman of the Small Business Subcommittee on Exports, Tax Policies and Special Problems, and that's how I got involved in this. It is an export problem and a special problem and—

Mr. Valentine. You conducted a hearing, didn't you?

Mr. Sisisky. Yes, sir, we conducted a hearing. I think when you hear all of this today, I think you'll be enlightened and want to do something about it. As I understand it, NIST comes under your jurisdiction. Nothing comes under our jurisdiction, but we're the kind of impulse that gets these special problems and hopefully gets the committee jurisdiction—

Mr. VALENTINE. Well, I have every confidence that you will find a way to overcome those problems of jurisdiction.

Mr. SISISKY. And I look forward to working with you in any way I can. Thank you, Mr. Chairman.

Mr. VALENTINE. Thank you very much.

Do you have any questions, Mr. Boehlert?

Mr. BOEHLERT. No questions. Thank you very much for a fine statement.

Mr. VALENTINE. Thank you, sir.

As citizens, we tend to take for granted that the products which we purchase are safe and of high quality, regardless of the country of origin. We do not think much about how the products we buy are tested, how they are certified and inspected, for quality assurance. Yet, ensuring that products are safe to use and meet the standards specified by each product by foreign countries is a tricky business for manufacturers, particularly now when international competition is reaching an all-time high.

In the United States, we have a diverse, largely uncoordinated system for testing and certification of commercial products. Testing and certification are done at hundreds of different Federal, State and private laboratories. These private laboratories are often small businesses that do not have the resources to address the constraints imposed on them by foreign trade blocks. Yet, cumulatively, they are a multi-million dollar business.

This diverse set of laboratories are accredited by yet another set of Government and private organizations such as the National Voluntary Laboratory Accreditation Program and the National Institute of Standards and Technology and the American Association for Laboratory Accreditation. Accreditation of quality assurers is handled in much the same way.

The lack of a focal point in the United States for product testing and certification is a concern, particularly when dealing with international competitors. Consider, for instance, the European Community, EC, which is developing testing and certification standards and procedures that will replace more than a dozen bilateral agreements currently in use between the United States and foreign countries. The EC's current position is that initially only European labs will be allowed to approve products that require independent, third party certification. This, of course, places the United States' manufacturers and private laboratories at a significant competitive disadvantage. Mutual recognition of each other's product testing and certification must occur not only between the United States and Europe, but also between the United States and the other major trading partners.

It is interesting to note that although the General Agreement of Tariffs and Trade, GATT, specifically includes provisions that deal with industrial standards, it does not mention conformity assessment requirements.

As we address these issues in detail, a word of caution is in order. We need to be careful that the product standards of the United States are not compromised while reaching an accommodation with other nations. In the United States, the marketplace, product liability laws, antitrust laws, as well as the voluntary standards system, all contribute to the certification of product safety and health. This combination of forces is not always present in other countries.

We have with us today experts with a wide range of backgrounds on the subject of national and international product testing, certification, and quality assurance. It is a pleasure to have our distinguished colleague, Congressman Sisisky, whom we have heard from out of order. He, as was stated, held a hearing on the 30th of April of this year on the international implications of testing and certification for small business. We look forward to working with him in attempting to address this problem.

From the Department of Commerce we welcome Dr. Thomas Deusterberg, Assistant Secretary of Commerce for International Economic Policy, who has just returned from a trip to Europe which included discussions in this area. He has been very active in dealing with the EC on trade policy.

Accompanying the Doctor is the Deputy Director of the National Institute of Standards and Technology, NIST, Mr. Ray Kammer. NIST, of course, is the Government focal point for standards and measurement issues.

On panels two and three we will have representatives from the private laboratory and manufacturing communities to give us some insight into their concerns and, hopefully, some concrete recommendations for future action. We welcome all here today.

Finally, let me say, before we start, I would like to make one final comment. Even though we are striving to gain mutual recognition of testing and certification with our international competitors, we do not believe that identical product standards in all countries are desirable or practical. Our challenge in the United States is to develop mutually acceptable criteria for assuring products destined for another country meet the importing country's standards before leaving the exporter's shores. The methods for obtaining this end and the amount of Government involvement required are the key issues that we would like to address here today.

Before I yield to our distinguished Republican ranking member of the subcommittee, I would like to announce that because of the fact that Mr. Mandela will address a Joint Session of Congress at 11:00 o'clock, we propose here to hear the testimony of the first panel and then recess to a time to be announced when the members will have an opportunity to be there for this—and others who have tickets—for this historic occasion.

Mr. Boehlert?

Mr. BOEHLERT. Thank you, Mr. Chairman.

The focus of this morning's hearing is, frankly, the most archane subject we will ever deal with. But international conformance and assessment rules are as significant as they are obscure. They are a foundation of foreign trade.

And like most foundations, we take note of this one now only because it is crumbling. The coalescing of the world into coherent, aggressive trade blocs is the death knell for business as usual. We have to admit that this foundation is settling unevenly, creating dangerous gaps and fissures.

The tricky part, of course, is figuring out how to shore it up. The methods used by other nations may not be appropriate here. After all, our voluntary conformance system has served us well, by and large.

So I throw the question out to today's witnesses, pretending to no personal expertise: how can we ensure that the U.S. remains an influential player in the setting of conformance rules? Just claiming that we've done all right up to now is not an acceptable answer; nor is turning our system over topsy-turvy to mimic one abroad. I hope our witnesses will present a reasonable middle ground.

Thank you, Mr. Chairman.

[The prepared statements of Hon. Norman Sisisky, and Hon. Jerry F. Costello follow:]

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Testomony of
CONGRESSMAN NORMAN SISISKY
Before the Subcommittee on
Science, Research and Technology

Tuesday, June 26, 1990

Thank you Congressman Valentine for allowing me this opportunity to testify before your subcommittee on this critical isuue to small business manufacturers.

My Small Business Subcommittee on Exports, Tax Policy and Special Problems held a hearing on April 30 in order to examine the certification problem facing small American laboratories who are looking to test products for export to the European Community.

A serious concern exists in the small laboratory community that their test results will not be acceptable in the E.C. Community. If this fear is realized, it will force American business to use European labs --a requirement the U.S. government does not make on European manufacturers.

Testing and certification of products and services assures the quality of American goods. Consider for a moment what we Americans do every morning of every day ... we wake up to the electric radio and then we turn on the electric light. The fixture switch and various wires must all be tested to assure safety and performance, prevent electrocution and fire, as well as assure sufficient power or brightness.

We brush our teeth knowing that the water has been tested to assure potability, and the faucet to assure performance. The toothpaste is tested to assure non-toxicity and efficacy.

Virtually every piece of metal, glass, electrical circuits, or plastic that we find in our everyday life must be laboratory tested to assure safety and performance.

Testing and certification pervade American life. Laboratories support billion dollar industries, yet labs are usually not considered to be an industry. Most often, they are thought of as a cost of doing business ....or an after thought in supporting the regulatory goals of a statute. It is important to remember that testing laboratories assure objectivity in the evaluation of products and services.

Our Subcommittee focused on the government's role in helping American laboratories become accredited in the European Community. Without EC accreditation, U.S. labs will be unable to test and certify American exports to the Common Market. European accreditation requirements present a serious problem for small- to medium-size labs.

Put simply, we found that small labs are concerned they will not be able to have their test results certified by the EC, nor do they believe they can gain EC approval by becoming subcontractors to European labs.

Products cannot go to market until they are tested and certified by a laboratory accredited to perform such testing. Under the emerging EC system, a U.S. manufacturer may be unable to use a U.S. laboratory to test his product for the export market.

Under the EC scheme U.S. laboratories cannot become "notified bodies". Without being a "notified body", a U.S. lab will not be able to test products for the European market. The U.S. system, on the other hand, is open, transparent and does not discriminate against non-U.S. laboratories. Many laboratories, for example, are certified by the FCC.

The problem, as expressed by representatives from the European Community, is that the EC Commission will have enough work accrediting European labs --- they do not believe they should accept responsibility for certifying U.S. labs. In an effort to resolve this problem the EC Commission will allow European "notified bodies" to subcontract with U.S. labs. Many small labs believe this solution will cut them out of the testing business.

Historically, laboratory certification of products and standards has been a private sector activity. Although this process has been adequate to meet domestic certification requirements, the EC's new testing requirements may necessitate greater U.S. Government involvement if American labs are to remain competitive.

Currently no single government or industry authority in the U.S has a program sufficient to evaluate U.S. laboratories. Presently in the private sector, we are seeing a proliferation of uncoordinated laboratory accreditation systems. Additionally, the National Institute of Standards and Technology (NIST) has a program which is small and under funded. In other words, there is no single body with which the EC can negotiate. I would hope, we in Congress can change this situation.

The ability of U.S. labs to test American products for the European market is at stake, I would hope we will find a way to help our U.S. products be more easily accepted in the European Community. We need to help our American labs achieve certification in the 1992 environment.

Mr. Chairman, thank you once again for allowing me to communicate my concerns. I look forward to assisting you develop a solution.

OPENING STATEMENT

BY U.S. REP. JERRY F. COSTELLO, ILLINOIS

COMMITTEE ON SCIENCE, SPACE AND TECHNOLOGY

SUBCOMMITTEE ON SCIENCE RESEARCH AND TECHNOLOGY

JUNE 26, 1990

Mr. Chairman, this hearing focuses on whether or not products that are tested in the U.S. be accepted in the international marketplace and if we can ensure that foreign countries accept testing by U.S. labs. I would like to extend a warm welcome for our colleague The Honorable Norman Sisisky (D-WV).

In order to have a strong marketplace the U.S. must approach the 21st Century without unnecessary trade barriers. It is also imperative that the U.S. have a unified approach when dealing with all countries

I welcome our witnesses and I thank you, Mr. Chairman, for calling this hearing.

Mr. **Valentine**. Thank you, sir.

As I stated, our first witnesses are the Honorable Thomas Deusterberg, Assistant Secretary for International Policy, U.S. Department of Commerce, and Mr. Raymond G. Kammer, Deputy Director of NIST. Welcome, gentlemen. Dr. Duesterberg.

STATEMENT OF THOMAS J. DEUSTERBERG, ASSISTANT SECRETARY FOR INTERNATIONAL POLICY, U.S. DEPARTMENT OF COMMERCE; AND RAYMOND G. KAMMER, DEPUTY DIRECTOR, NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

Mr. **Duesterberg**. Thank you very much, Mr. Chairman. First I want to commend you and your colleagues for having this hearing. This is an archane subject that's hard for all of us to master, but nonetheless is extremely important and is worth our attention.

I have a full statement I would like to ask be placed in the record, and perhaps I'll just take a few minutes to summarize my major points.

I come at this from a slightly different perspective than Mr. Kammer comes at this. Our principal interest in the International Trade Administration is to assure that standard setting and conformity assessment procedures are not an impediment to trade. We have felt from the very early stage that the integration of the European Community provides both an opportunity and a challenge, an opportunity because they will hopefully sweep away 12 separate standard-making and certification systems and replace them with one coherent system. With a market of 320 million people, the opportunity is for the American manufacturer and exporter to be able to build to one standard and test to one standard and, therefore, simplify his procedures for exporting. The challenge is to make sure that the way the new system in Europe is established does not provide an impediment to trade.

So, given this background, Secretary Mosbacher met with his counterpart, Commissioner Bangemann, last May in Brussels and established an ongoing dialogue to discuss the establishment of the new European standards and certification system. We've had two formal series of talks with the Europeans, the first being on standards and the second, a couple of weeks ago, on issues related to certification. We feel it's been a good dialogue and we've been able to have a fairly frank discussion with the European Commission about some of the problems we see arising as they contemplate and put into place their new system.

As I said, two weeks ago I led a U.S. delegation to Brussels to discuss with the Commission EC's approach to testing, certification, and other conformity assessment issues for products covered by the EC's new approach directive. At the outset of our discussions, the EC stated their conformity assessment system would not be a barrier to trade. However, the EC also made it clear that there are other areas where access granted to the U.S. will need to be based on some type of negotiated agreement.

I would note here that the EC has not yet put into place their new conformity assessment procedure. The Commission has a fairly good idea of what they want to do, but they have to get this approved by the Council. So what we are trying to do in our meetings is to gather as much information as we could, have discussions with all concerned parties in the United States, including industry, including this opportunity to discuss with you and some of your colleagues, and then go back to the Community before they put their final system in place with some suggestions as to how we think the best way to do it, in a way that doesn't preclude or hinder trade.

Well, let me give something of a summary of what we learned two weeks ago. The Commission confirmed that members states could only designate notified bodies—that is, bodies accredited to perform third party certifications, accreditations or approvals under EC directives from within their political boundaries, that is, within their own states—and that no subsidiaries or related enterprises located outside the EC can perform these functions. This would exclude U.S. test labs performing such testing and certification functions unless mutual recognition agreements are negotiated.

On the topic of mutual recognition agreements, the EC stated that such agreements would be negotiated sector by sector between the EC Commission and the U.S. body which is deemed equivalent by the EC for it's ability to oversee the competence of the U.S. body and to develop coherence and uniformity of acceptance in the United States.

I would note that the Commission does not appear at this time to demand that mutual recognition agreements always be on a government-to-government basis. Six months ago it appeared that they were moving in that direction. The Commission, in other words, seems ready to negotiate agreements with both public and private sector testing and certification bodies outside the Community.

However, the EC continues to seek what they call a balanced commercial situation in these agreements to be determined on the basis of several factors, including the level of existing exports or potential exports on a sectoral basis and the lack of technical obstacles for EC exports to the entire third country national market. The EC sees the proposed recognition agreements as a means to assure access to unified national markets, namely, the entire U.S. market. In this regard, the EC officials pressed us to assure that state and local certification requirements would not impede access to EC products. Such access appears to be an area for negotiation with the European Commission.

We also discussed the role and the function of the European Organization for Testing and Certification, or the EOTC, which will cover nonregulated products in the European Community. According to the EC, foreign participation in the EOTC may be permitted in what are going to be called agreements approved within the EOTC. However, the Commission emphasized that interested U.S. entities, whether they be labs, companies or professional societies, will most likely need to show their ability to make their participation in the EOTC what they quoted as "commercially interesting" to the agreements groups in order to secure participation.

Based on our discussions with the European Community and interest expressed from parts of the U.S. private sector, there are several important areas where the U.S. Government and private sector should direct their attention. We found that access to the EC notified bodies may be very important to U.S. exports. The Europeans have been very insistent that the U.S. agree to bilateral reciprocity to gain access to the EC's system of testing and certification. I don't want to highlight too much the word "reciprocity" because it's a fluid term that we can perhaps elaborate on in our discussion.

We are looking at their proposal very closely, but at this time we see no reason for us to depart from our dependence on the principle of national treatment which has made our markets so open to EC products and to EC product tests and certificates. We will continue to advocate that Europe, in turn, apply national treatment to U.S. product testing and certification.

However, Mr. Chairman, U.S. as well as European manufacturers deserve more coherence and uniformity in the U.S. regulatory system for product approvals and acceptances. Differences in requirements at the Federal and local level throughout the U.S. market are very costly, requiring multiple tests and certificates and multiple production runs. There is a need to examine how these differing U.S. systems undercut the competitiveness of U.S. industry in the U.S. market as well as in international markets.

There is also reason to look at the coherence of programs in the U.S. Federal Government sector. The current system has a variety of acceptance programs, as I think you noted in your opening statement. This creates the need for multiple capabilities throughout the economy which may be unnecessarily costly to the U.S. business community. The U.S. Federal Government reliance on one consistent set of standards and a unified accreditation program for federally-regulated products may be a positive contribution to U.S. competitiveness overall.

We also found a very great reliance in Europe on quality systems inspections and their reliance on the ISO 9000 series of standards for quality systems. This will become the basis for international trade with the EC on construction products, medical devices, personal protective equipment and telecommunications products—just to name a few.

Mr. Chairman, I am concerned that we have given scant attention in the U.S. to the consistency and strength of our quality assurance and quality accreditation system. Quality assurance is going to be very important and we need to develop a program in the U.S. that responds directly to this need.

Mr. Chairman, again I commend your committee for conducting hearings on this very important subject which is key to U.S. competitiveness. The Department intends to initiative extensive consultations with industry sectors affected by the European Community programs which will complement the workshops that Under Secretary White of the Technology Administration announced in your hearings last week. The goal of these industry consultations is to develop the appropriate U.S. position toward the EC's 1992 program and to advance our commercial interests. I will be pleased to work with this committee and your staff to see that this goal is achieved.

[The prepared statement of Thomas Deusterberg follows:]

STATEMENT OF
THOMAS J. DUESTERBERG
ASSISTANT SECRETARY FOR INTERNATIONAL ECONOMIC POLICY
U.S. DEPARTMENT OF COMMERCE

HOUSE SCIENCE COMMITTEE HEARINGS ON
INTERNATIONAL STANDARDIZATION

JUNE 26, 1990

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE, I AM PLEASED TO BE HERE TODAY TO DISCUSS THE EUROPEAN COMMUNITY'S APPROACH TO TESTING AND CERTIFICATION AND THE ROLE OF THE U.S. GOVERNMENT IN THIS CRITICAL AREA. I APPRECIATE THE OPPORTUNITY TO TESTIFY TOGETHER WITH SEVERAL EXPERTS REPRESENTING PRIVATE LABORATORIES AND TESTING AND ACCREDITATION COMPANIES.

U.S. MARKET ACCESS RELATED TO EC TESTING AND CERTIFICATION REQUIREMENTS IS A PRIORITY OF THE ADMINISTRATION. MOST INTERNATIONAL TRADE, AND CERTAINLY ALL TRADE IN INDUSTRIAL PRODUCTS, DEPENDS ON THE ABILITY OF MANUFACTURERS TO CERTIFY THAT THEIR EXPORTS REFLECT THE QUALITY AND SPECIFICATIONS REQUIRED BY THE BUYER. IF LOW COST TESTING AND CERTIFICATION PROCEDURES ARE NOT ACCESSIBLE, THEN THE EXPORT MARKET IS NOT ACCESSIBLE.

THE U.S. GOVERNMENT BELIEVES THAT AN OPEN MARKET IN THE EC PERMITTING ENTRY OF GOODS THAT MEET BASIC HEALTH, SAFETY, AND ENVIRONMENTAL REQUIREMENTS OUTLINED BY EC DIRECTIVES IS IN THE INTEREST OF ALL PARTIES. FURTHER, TESTING AND CERTIFICATION SCHEMES AS THEY ARE BEING DEVELOPED IN THE EC SHOULD NOT BE USED AS A TRADE BARRIER TO U.S. OR ANY NON-EC PRODUCT.

OPPORTUNITIES FOR U.S. BUSINESS

THE EC'S 1992 PROGRAM PRESENTS AN OPPORTUNITY AS WELL AS A CHALLENGE TO U.S. BUSINESS. AN INTEGRATED MARKET OF 325 MILLION CONSUMERS AND A COLLECTIVE GNP OF APPROXIMATELY $4 TRILLION MAKE THE EC THE SINGLE LARGEST MARKET FOR U.S. EXPORTS. FURTHER, WITH THE DEVELOPMENT OF HARMONIZED STANDARDS, TESTING, AND CERTIFICATION PROCEDURES, THE PROCESS OF SELLING TO THE EC SHOULD ULTIMATELY BE SIMPLIFIED AND LESS COSTLY FOR U.S. COMPANIES.

U.S. MANUFACTURERS HAVE IDENTIFIED THE TESTING AND CERTIFICATION AREA AS ONE OF THE MOST IMPORTANT ELEMENTS OF THE EC 1992 PROGRAM. AFTER 1992 PRODUCTS IN A WIDE RANGE OF SECTORS WILL HAVE TO BE CERTIFIED AS BEING IN CONFORMITY WITH BASIC SAFETY, HEALTH, AND ENVIRONMENTAL REQUIREMENTS EMBODIED IN EC-WIDE DIRECTIVES BEFORE THEY CAN BE PLACED ON THE EC MARKET. THE EC'S PROPOSED POLICIES FOR ASSESSING PRODUCT CONFORMITY HAVE RAISED NUMEROUS QUESTIONS AND POTENTIAL PROBLEMS FOR U.S. FIRMS SEEKING ACCESS TO THE EC MARKET.

BACKGROUND AND RECENT DEVELOPMENTS IN TESTING AND CERTIFICATION

PRIOR TO THE MID-1980'S, THE EC LACKED A MECHANISM FOR MUTUAL RECOGNITION OF TESTING AND PRODUCT APPROVAL, RELYING INSTEAD ON INDIVIDUAL MEMBER STATE REGULATIONS THAT WERE COSTLY AND CUMBERSOME FOR COMPANIES NOT BASED IN THE EC. IN THE MID-1980'S, THE EC LAUNCHED A NEW, MORE HARMONIZED APPROACH TO STANDARDS, TESTING, AND

CERTIFICATION. FOR PRODUCT STANDARDS, THE EC DEVELOPED A "NEW APPROACH", ISSUING DIRECTIVES WHICH STIPULATED "ESSENTIAL REQUIREMENTS" TO PRESERVE HEALTH, SAFETY, AND ENVIRONMENTAL CONDITIONS FOR CERTAIN PRODUCTS. THE DEVELOPMENT OF TECHNICAL STANDARDS, SPECIFICATIONS, AND TEST METHODS TO ASSESS CONFORMITY WITH ESSENTIAL REQUIREMENTS WAS CONTRACTED TO EUROPEAN REGIONAL STANDARDS ORGANIZATIONS - PRIMARILY TO CEN, CENELEC, AND ETSI. WHILE MANUFACTURER COMPLIANCE WITH HARMONIZED STANDARDS IS VOLUNTARY, IT PROVIDES AN ASSUMPTION OF CONFORMITY TO EC REQUIREMENTS.

THE EC PLANS TO IMPLEMENT A HARMONIZED APPROACH TO TESTING AND CERTIFICATION, AS WELL AS TO PROVIDE FOR THE MUTUAL RECOGNITION OF MEMBER STATE CERTIFICATIONS THAT THE LEGISLATED SAFETY REQUIREMENTS HAVE BEEN MET BY MANUFACTURED PRODUCTS. THE NEW SYSTEM WOULD ALLOW A CHOICE OF METHODS TO ENSURE PRODUCT CONFORMITY, FROM MANUFACTURER'S DECLARATION OF CONFORMITY TO THIRD PARTY TESTING AND SURVEILLANCE, DEPENDING ON THE TYPE OF PRODUCT. THE PROPOSED EC TESTING AND CERTIFICATION SYSTEM IS DESIGNED TO ASSURE UNIFORM ACCESS FOR REGULATED PRODUCTS IN THE EC THROUGH THE USE OF A SINGLE SAFETY MARK.

BECAUSE OF THE IMPORTANCE OF TESTING AND CERTIFICATION TO OUR $90 BILLION OF EXPORTS TO THE EUROPEAN COMMUNITY, COMMERCE UNDER SECRETARY FOR INTERNATIONAL TRADE FARREN LAST DECEMBER 14TH PRESENTED TO THE EC COMMISSION A PAPER DETAILING THE U.S. GOVERNMENT'S VIEWS ON THE EC

PROPOSALS, WHICH INCORPORATED U.S. PRIVATE SECTOR CONCERNS. ON DECEMBER 21, THE EC COUNCIL ADOPTED A RESOLUTION TO SUPPORT THE OVERALL OBJECTIVES OF THE COMMISSION'S "GLOBAL APPROACH" DOCUMENT AND ASKED THE EC COMMISSION TO WORK ON DEVELOPING NEGOTIATING MANDATES FOR MUTUAL RECOGNITION AGREEMENTS WITH THIRD COUNTRIES.

THE U.S. BELIEVES THAT THE NEW EC REGULATIONS PERTAINING TO CONFORMITY ASSESSMENT SHOULD PROMOTE INTERNATIONAL TRADE AND AVOID DISRUPTIONS OF EXPORTS FROM THIRD COUNTRIES BY PROVIDING FOR THE RECOGNITION OF PRODUCT TESTING IN THIRD COUNTRIES. IN ADDITION, WE HAVE HAD CONCERNS THAT THIRD COUNTRY TESTING LABORATORIES WOULD NOT BE ABLE TO BECOME "NOTIFIED BODIES", ENTITIES AUTHORIZED TO PERFORM TESTING TO DEMONSTRATE COMPLIANCE TO EC REQUIREMENTS, AND THAT THE EC MIGHT REQUIRE RECIPROCAL COMMERCIAL GUARANTEES FOR MUTUAL RECOGNITION THAT GO BEYOND WHAT IS NECESSARY TO ASSURE SAFETY AND PROTECT CONSUMERS.

U.S. MANUFACTURERS WANT TO ENSURE THAT THEY WILL BE ABLE TO HAVE THEIR PRODUCTS APPROVED FOR THE EC MARKET QUICKLY AND AT THE LOWEST POSSIBLE COST. THEY FEAR THAT THE EC'S APPROVAL PROCEDURES MAY REQUIRE COSTLY TESTS TO BE CARRIED OUT IN THE EC TO DEMONSTRATE PRODUCT SAFETY AND CONFORMITY TO THE ESSENTIAL REQUIREMENTS IN EUROPE; TESTS WHICH IN MANY CASES WERE ALREADY PERFORMED FOR U.S. MARKET REQUIREMENTS. U.S. TESTING LABORATORIES ALSO FEAR THEY WILL BE LESS COMPETITIVE THAN EUROPEAN LABS UNLESS THEY ARE ALLOWED TO PERFORM TESTS TO DEMONSTRATE CONFORMITY TO EUROPEAN REQUIREMENTS.

JUST TWO WEEKS AGO, I LED A U.S. DELEGATION TO BRUSSELS TO DISCUSS WITH OFFICIALS OF THE EC COMMISSION THE EC'S APPROACH TO TESTING, CERTIFICATION, AND OTHER CONFORMITY ASSESSMENT ISSUES FOR PRODUCTS COVERED BY THE EC'S NEW APPROACH DIRECTIVES. THE PRIMARY PURPOSE FOR THIS MEETING WAS TO OBTAIN ANSWERS FROM THE COMMISSION TO THE QUESTIONS I HAVE OUTLINED FOR YOU REGARDING THE IMPACT OF EC TESTING AND CERTIFICATION REQUIREMENTS ON ACCESS FOR U.S. PRODUCTS TO THE EC MARKET.

I WANT TO SHARE THE RESULTS OF THESE DISCUSSIONS WITH THE SUBCOMMITTEE. FIRST, HOWEVER, LET ME FILL YOU IN ON OUR EXPERIENCE TO DATE WITH THE EVOLVING EC SYSTEM IN THE PRODUCT SAFETY AREA.

THE EVOLVING EC SYSTEM FOR PRODUCT TESTING AND CERTIFICATION

TENS OF THOUSANDS OF U.S. PRODUCTS ENTERING FOREIGN COMMERCE EVERY YEAR ARE TESTED FOR COMPLIANCE FOR THE FOLLOWING PURPOSES:

- LEGISLATED OR OTHER FORM OF REGULATORY REQUIREMENTS TO MAINTAIN A LEVEL OF SAFETY AND HEALTH;

- LEGISLATED OR OTHER FORM OF REGULATORY REQUIREMENTS FOR INTEROPERABILITY OR OTHER ACCEPTED PRODUCT CHARACTERISTICS;

- PRIVATE CONTRACTUAL REQUIREMENTS BETWEEN WILLING BUYERS AND SELLERS.

THE ANNEX LISTS THE PRODUCTS COVERED BY THE EC 1992 PROGRAM TO CREATE A SINGLE MARKET FOR TESTING AND CERTIFICATION. IN MOST CASES, TESTING REQUIREMENTS ARE A NORMAL CONDITION OF DOING BUSINESS. HOWEVER, IN MANY CASES, TESTING AND CERTIFICATION REQUIREMENTS ARE COSTLY AND CAN PRESENT A BARRIER TO TRADE.

EC TESTING AND CERTIFICATION ISSUES

TO DATE, ONLY ONE EC PRODUCT SAFETY DIRECTIVE HAS BEEN IMPLEMENTED, AND IT PERTAINS TO TOYS. AS OF JANUARY 1, 1990, THE CE MARK MUST APPEAR ON ALL TOYS MARKETED IN THE EUROPEAN COMMUNITY TO SIGNIFY THAT ESSENTIAL REQUIREMENTS CONTAINED IN THE EC DIRECTIVE ON TOYS HAVE BEEN MET. UNDER THIS DIRECTIVE, U.S. MANUFACTURERS CAN CHOOSE TO SELF-CERTIFY COMPLIANCE WITH THE DIRECTIVE BY REFERENCE TO CEN/CENELEC STANDARDS AND ISSUANCE OF A MANUFACTURER'S DECLARATION OF CONFORMITY. THIRD PARTY INVOLVEMENT IN CERTIFICATION IS REQUIRED ONLY IF THE MANUFACTURER CHOOSES NOT TO REFERENCE CEN/CENELEC STANDARDS.

THIRTY NOTIFIED BODIES HAVE BEEN APPROVED IN THE SIX EC COUNTRIES THAT HAVE IMPLEMENTED THE EC TOYS DIRECTIVE. SOME OF THESE LABS ARE OWNED BY NON-EC INTERESTS. THE EC DOES NOT ALLOW THIRD PARTY CERTIFICATIONS TO BE ISSUED OUTSIDE THE GEOGRAPHIC BOUNDARIES OF THE EC. AT THIS TIME, NO LABORATORY OR OTHER ENTITY MAY CERTIFY TEST RESULTS TO THE EC'S REGULATORY REQUIREMENTS IF IT IS PERFORMING ITS CERTIFYING ACTIVITY OUTSIDE THE EUROPEAN COMMUNITY.

THUS, THERE IS ABSOLUTELY NO PROVISION AT THIS TIME FOR A NON-EC BASED TEST HOUSE OR PRODUCT CERTIFIER TO BECOME A NOTIFIED BODY OR ISSUE AN EC CERTIFICATE. BUT IT IS ALSO TRUE THAT THE U.S. MANUFACTURER CAN RELY ON TEST RESULTS FROM A LAB OF HIS CHOICE, EITHER U.S. OR FOREIGN, AS THE BASIS FOR THE MANUFACTURER'S DECLARATION OF CONFORMITY. IN PRINCIPLE, THEN, U.S. TESTING CAN BE USED IN THE TOYS DIRECTIVE IN CONJUNCTION WITH THE U.S. MANUFACTURER'S DECLARATION OF CONFORMITY.

THE NEXT EC PRODUCT SAFETY DIRECTIVE IS SCHEDULED TO BECOME EFFECTIVE IN DECEMBER, 1990 -- CONSTRUCTION PRODUCTS. IN THIS CASE, MANY PRODUCTS WILL BE PERMITTED TO ENTER THE EC BASED ON THE MANUFACTURER'S DECLARATION OF CONFORMITY -- SELF-CERTIFICATION TO EC STANDARDS. BUT THERE IS A GREAT RELIANCE ON QUALITY SYSTEMS INSPECTIONS WHICH IS AN EXPENSIVE PROCESS WHEN PERFORMED BY MANUFACTURERS THEMSELVES BUT CAN BE PROHIBITIVELY EXPENSIVE IF EC QUALITY INSPECTORS ARE REQUIRED TO PERFORM THESE PLANT INSPECTIONS TO OBTAIN CERTIFICATION.

AS NOTED IN THE ANNEX THERE ARE ALSO "OLD APPROACH" DIRECTIVES WHICH DO NOT RELY ON THE CE MARK OR VOLUNTARY STANDARDS, AND THE MARKETING OF PRODUCTS IS ENTIRELY CONTROLLED BY THE REGULATORY COMMITTEES OF THE EC COMMISSION. IN THIS CASE, A U.S. MANUFACTURER MUST COMPLY WITH THESE REGULATORY REQUIREMENTS. THESE REQUIREMENTS RELY UPON TESTING AND CONFORMITY ASSESSMENT BASED ON LEGISLATED CODES OF GOOD PRACTICE SIMILAR TO "GOOD CLINICAL PRACTICES," "GOOD MANUFACTURING PRACTICES", AND "GOOD LABORATORY PRACTICES." PRODUCTS AFFECTED IN THIS AREA ARE

CHEMICALS, PHARMACEUTICALS AND FOOD PROCESSING. IN THE CASE OF PRODUCTS AFFECTED BY "OLD APPROACH" DIRECTIVES, WE UNDERSTAND THAT U.S. TEST RESULTS COMPLETED AS A PART OF THE MANUFACTURERS SUBMISSIONS TO THE EC COMMISSION FOR PRODUCT APPROVAL WILL BE ACCEPTED.

IN SUMMARY, NO EC PRODUCT DIRECTIVE HAS BEEN IMPLEMENTED TO DATE THAT DENIES THE U.S. MANUFACTURER THE ABILITY TO TEST IN THE U.S. AT THIS STAGE OF THE DEVELOPING EC SYSTEM, U.S. TEST LABS CAN PERFORM TESTS FOR EC REGULATED PRODUCTS WHERE MANUFACTURERS ARE ALLOWED TO SELF-CERTIFY COMPLIANCE BY MEANS OF A MANUFACTURER'S DECLARATION OF CONFORMITY.

AS YET, THERE IS NO REQUIREMENT TO USE A NOTIFIED BODY. HOWEVER, THIS WILL NOT BE THE CASE IN THE NEAR FUTURE, AND THIS RAISES CONCERNS OVER THE CRITERIA THE EC WILL APPLY FOR MUTUAL RECOGNITION WITH U.S. TESTING AND CERTIFYING BODIES. IN THE FUTURE, SOME OF THE EC REGULATIONS WILL CLEARLY REQUIRE INDEPENDENT TESTING AND WILL ONLY PROVIDE FOR ACCEPTANCE OF U.S. TEST RESULTS OR THIRD PARTY CERTIFICATIONS UNDER SPECIAL CIRCUMSTANCES, SUCH AS DESIGNATION OF "NOTIFIED BODY" STATUS.

THE EUROPEAN COMMUNITY HAS STATED THAT NOTIFIED BODIES CAN BE DESIGNATED IN THE U.S. AND THAT OTHER MEANS OF COMPLIANCE CAN BE DEVELOPED TO AVOID DISRUPTION OF INTERNATIONAL TRADE. HOWEVER, THE EC HAS NOT DEFINED THE MEANS FOR INTERESTED TEST HOUSES AND CERTIFIERS TO ACCESS THESE PROGRAMS.

THE EC HAS ALSO SAID THAT ACCREDITATION OF U.S. LABORATORIES AND CERTIFICATION BODIES WILL ONLY BE PERMITTED ON THE BASIS OF FORMAL "MUTUAL RECOGNITION" AGREEMENTS. SUCH AGREEMENTS WILL BE BASED ON THREE CRITERIA:

- THE COMPETENCE OF THE THIRD COUNTRY BODIES IS AND REMAINS ON A PAR WITH THAT REQUIRED OF THEIR COMMUNITY COUNTERPARTS;
- THE MUTUAL RECOGNITION ARRANGEMENTS ARE CONFINED TO REPORTS, CERTIFICATES, AND MARKS DRAWN UP AND ISSUED DIRECTLY BY THE BODIES DESIGNATED IN THE AGREEMENTS;
- IN CASES WHERE THE COMMUNITY WISHES TO HAVE ITS OWN BODIES RECOGNIZED, THE AGREEMENTS ESTABLISH A BALANCED SITUATION WITH REGARD TO THE ADVANTAGES DERIVED BY THE PARTIES IN ALL MATTERS RELATING TO CONFORMITY ASSESSMENT FOR THE PRODUCTS CONCERNED.

THE LAST CRITERION RAISES BOTH PRACTICAL AND POLICY PROBLEMS FOR THE U.S. SOME U.S. TESTING LABS COMPLAIN THAT WITHOUT SUCH ACCREDITATION, THEY WILL BE PLACED AT A COMPETITIVE DISADVANTAGE RELATIVE TO THEIR EC COUNTERPARTS.

THE DEVELOPMENT OF MECHANISMS FOR BILATERAL RECOGNITION OF TESTING AND CERTIFICATION WAS THE SUBJECT OF DISCUSSION AT THE RECENTLY-CONCLUDED MEETINGS ON TESTING AND CERTIFICATION IN BRUSSELS ON JUNE 13-14.

RESULTS OF THE JUNE 13-14 MEETING

ON JUNE 13-14, I LED A DELEGATION WITH REPRESENTATIVES OF U.S. FEDERAL GOVERNMENT AGENCIES THAT HAVE RESPONSIBILITY FOR REGULATING THE SAFETY OF VARIOUS PRODUCTS IN THE U.S. MARKET. AGENCIES REPRESENTED INCLUDED THE OCCUPATIONAL HEALTH AND SAFETY ADMINISTRATION, DEPARTMENT OF LABOR, THE FOOD AND DRUG ADMINISTRATION, THE NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY, DEPARTMENT OF COMMERCE, AND THE DEPARTMENT OF DEFENSE. THE U.S. TRADE REPRESENTATIVE AND THE DEPARTMENT OF STATE WERE ALSO REPRESENTED.

AT THE OUTSET OF OUR DISCUSSIONS, THE EC STATED THAT THEIR CONFORMITY ASSESSMENT SYSTEM WOULD NOT BE A BARRIER TO TRADE. THE EC EXPLAINED, HOWEVER, THAT THE ACCESS GRANTED THE U.S. MUST BE APPROVED BY THE COUNCIL, BOTH IN THE CASE OF SPECIFIC EC DIRECTIVES AND IN A MANDATE FOR NEGOTIATION OF MUTUAL RECOGNITION AGREEMENTS. DISCUSSIONS BY THE EC DELEGATION CLARIFIED AND GAVE DETAILS ON THE EC APPROACH TO CONFORMITY ASSESSMENT, PARTICULARLY EMPHASIZING NOTIFIED BODIES, SUBCONTRACTING, EC MARK, AND MUTUAL RECOGNITION AGREEMENTS.

ON THE SUBJECT OF NOTIFIED BODIES, THE EC OFFICIALS DISCUSSED THE RESPONSIBILITIES OF MEMBER STATES AND THE EC COMMISSION. THE EC COMMISSION IS CHARGED WITH ESTABLISHING THE LEGISLATION TO IMPLEMENT EC DIRECTIVES, REVIEWING MEMBER STATE APPROVAL OF NOTIFIED BODIES, DEVELOPING A FORUM FOR MEMBER STATES' NOTIFIED BODIES TO SHARE

INFORMATION (THIS IS NOT YET ESTABLISHED), AND INITIATING INVESTIGATIONS OF ANY PROBLEMS WITH THE MEMBER STATE SYSTEMS.

THE MEMBER STATES OVERSEE THE ACTIVITIES OF THE NOTIFIED BODIES AND IMPLEMENT AND ENFORCE NATIONAL LEGISLATION EMBODYING ESSENTIAL REQUIREMENTS AND CONFORMITY ASSESSMENT. MEMBER STATE GOVERNMENTS AND ACCEPTANCE BODIES FOR REGULATED PRODUCTS ARE OBLIGATED TO RECOGNIZE THE EC MARK ON PRODUCTS WHICH HAVE BEEN APPROVED BY NOTIFIED BODIES. NOTIFIED BODIES' CERTIFICATION UNDER THIS SYSTEM MUST BE ACCEPTED THROUGHOUT THE EC.

NOTIFIED BODIES WILL BE PERMITTED TO ENTER INTO SUBCONTRACTING ARRANGEMENTS IN ORDER TO EXTEND THEIR ABILITY TO PROVIDE SERVICES. SUBCONTRACTING CAN EXTEND ONLY TO NONEVALUATIVE ACTIVITIES OF NOTIFIED BODIES. THE COMMISSION CLEARLY STATED THAT SUBCONTRACTING CANNOT ENCOMPASS THE EVALUATION OF TEST RESULTS, OR THE ACTUAL CERTIFICATION OF PRODUCTS. SUBCONTRACTING ARRANGEMENTS MUST BE MAINTAINED IN COMPLIANCE WITH EN 45000 STANDARDS FOR LABORATORY ACCREDITATION, AND IN COMPLIANCE WITH EC DIRECTIVES.

IN THE AREA OF THIRD PARTIES BECOMING NOTIFIED BODIES, THE EC STATED THAT MEMBER STATES CAN DESIGNATE NOTIFIED BODIES FROM WITHIN THEIR POLITICAL BOUNDARY, AND THAT NO SUBSIDIARIES OR RELATED ENTERPRISES LOCATED OUTSIDE THE EC CAN PERFORM THIRD PARTY CERTIFICATIONS, ACCREDITATIONS OR APPROVALS OF ANY KIND. THIS WOULD EXCLUDE U.S. TEST LABS PERFORMING SUCH TESTING AND CERTIFICATION FUNCTIONS, UNLESS MUTUAL RECOGNITION AGREEMENTS ARE NEGOTIATED.

ON THE TOPIC OF MUTUAL RECOGNITION AGREEMENTS, THE EC STATED THAT SUCH AGREEMENTS WOULD BE NEGOTIATED SECTOR BY SECTOR BETWEEN THE EC COMMISSION AND THE U.S. BODY DEEMED "EQUIVALENT" BY THE EC FOR ITS ABILITY TO OVERSEE COMPETENCE OF U.S. BODIES, AND DEVELOP COHERENCE AND UNIFORMITY OF ACCEPTANCE IN THE UNITED STATES. FORMAL MUTUAL RECOGNITION AGREEMENTS WILL COVER ONLY THE CONDITIONS AND RESPONSIBILITIES FOR ESTABLISHING NOTIFIED BODIES IN A THIRD COUNTRY. I WOULD NOTE THAT THE COMMISSION DOES NOT APPEAR TO DEMAND THAT MUTUAL RECOGNITION AGREEMENTS ALWAYS BE ON A GOVERNMENT TO GOVERNMENT BASIS. THE COMMISSION, IN OTHER WORDS, SEEMS READY TO NEGOTIATE AGREEMENTS WITH BOTH PUBLIC AND PRIVATE SECTOR TESTING AND CERTIFICATION BODIES OUTSIDE THE COMMUNITY.

THESE MUTUAL RECOGNITION AGREEMENTS WILL BE NEGOTIATED SECTOR BY SECTOR AND WILL CONFER ON A NOTIFIED BODY APPROVAL OF ONLY THOSE FUNCTIONS FOR WHICH IT DEMONSTRATES COMPETENCY. UNDER THE TERMS OF A MUTUAL RECOGNITION AGREEMENT, THE U.S. MARKETPLACE AND ITS ACCEPTANCE BODIES MUST ACCEPT THE CERTIFICATES OF ALL EC NOTIFIED BODIES APPROVED BY THE EC FOR THE SECTORS.

THE EC COMMISSION EMPHASIZED ITS GOAL OF TRANSFERRING TECHNICAL COMPETENCE TO THE NOTIFIED BODIES. ADDITIONALLY, THE EC SEEKS A "BALANCED" COMMERCIAL SITUATION, WHICH DEPENDS ON FACTORS INCLUDING THE LEVEL OF EXISTING EXPORTS OR POTENTIAL EXPORTS ON A SECTOR BASIS AND THE LACK OF TECHNICAL OBSTACLES FOR EC EXPORTS FOR THE ENTIRE THIRD COUNTRY NATIONAL MARKET.

THE COMMISSION SAID THE PROPOSED RECOGNITION AGREEMENTS WERE A MEANS TO ASSURE THAT THE EC COULD GAIN ACCESS TO UNIFIED NATIONAL MARKETS -- NAMELY THE ENTIRE U.S. MARKET. IN THIS REGARD, THE EC PRESSED THE U.S. SIDE TO ASSURE THAT STATE AND LOCAL CERTIFICATION REQUIREMENTS WOULD NOT IMPEDE ACCESS TO EC PRODUCTS. SUCH ACCESS APPEARS TO BE AN AREA FOR NEGOTIATION WITH THE EC.

THE U.S. GOVERNMENT RESTATED ITS STRONG PREFERENCE FOR NATIONAL TREATMENT RATHER THAN THE EC'S PRINCIPLE OF SEEKING A "BALANCED" SITUATION -- WHICH IMPLIES A FORM OF RECIPROCITY. FINALLY, ON THE TOPIC OF THE EUROPEAN ORGANIZATION FOR TESTING AND CERTIFICATION (EOTC), THE COMMISSION STATED THAT ON APRIL 25, A MEMORANDUM OF UNDERSTANDING HAD BEEN SIGNED BETWEEN THE COMMISSION AND CEN/CENELEC FOR THE CREATION OF THE EOTC. AS OF JUNE 1, A SMALL EOTC STAFF HAD BEEN ESTABLISHED, AND THAT AN EOTC COUNCIL AND ORGANIZATIONAL GROUPS WOULD BE FORMED BY EARLY 1991. THE PURPOSE OF THE EOTC IS TO PROMOTE A EUROPEAN FOCUS FOR THE PRIVATE SECTOR BY PROMOTING MUTUAL RECOGNITION OF TESTS, PROCEDURES, AND QUALITY SYSTEMS FOR NON-REGULATED PRODUCTS IN THE EC.

AS TO FOREIGN PARTICIPATION IN THE EOTC, THE ANSWER WAS MIXED. IN GENERAL, NO FOREIGN REPRESENTATION WOULD BE POSSIBLE ON THE EOTC COUNCIL, THE SECTOR COMMITTEES, OR THE FUNCTIONAL COMMITTEES, ALTHOUGH FOREIGN PARTICIPATION IN AN AGREEMENTS GROUP OF THE EOTC MAY BE PERMITTED. FOREIGN ACCESS TO THE SECTOR COMMITTEES WOULD BE THROUGH THE AGREEMENTS GROUPS.

THE EC COMMISSION DENIED THAT THE EOTC WILL EVER BE AN ACCREDITING AUTHORITY. THE EC COMMISSION ALSO EMPHASIZED THAT IT IS MOST LIKELY THAT INTERESTED U.S. ENTITIES (WHETHER LABS, COMPANIES, OR PROFESSIONAL SOCIETIES) WOULD NEED TO SHOW THEIR ABILITY TO MAKE THEIR PARTICIPATION IN THE EOTC "COMMERCIALLY INTERESTING" TO THE AGREEMENTS GROUPS IN ORDER TO SECURE PARTICIPATION.

CONCLUSIONS

IN SUMMARY, BASED ON OUR DISCUSSIONS WITH THE EUROPEAN COMMUNITY COMMISSION AND INTEREST EXPRESSED FROM PARTS OF THE U.S. PRIVATE SECTOR, THERE ARE SEVERAL IMPORTANT AREAS WHERE U.S. GOVERNMENT AND PRIVATE SECTOR MUST DIRECT THEIR ATTENTION.

WE FOUND THAT ACCESS TO THE EC NOTIFIED BODIES MAY BE VERY IMPORTANT TO U.S. EXPORTS. THE EUROPEANS HAVE BEEN VERY INSISTENT THAT THE UNITED STATES AGREE TO BILATERAL RECIPROCITY TO GAIN ACCESS TO THE EC SYSTEM OF TESTING AND CERTIFICATION. WE ARE LOOKING AT THEIR PROPOSAL VERY CLOSELY BUT AT THIS TIME SEE NO REASON FOR US TO DEPART FROM OUR DEPENDENCE ON THE PRINCIPLE OF NATIONAL TREATMENT WHICH HAS MADE OUR MARKET SO OPEN TO EC PRODUCTS AND EC PRODUCT TESTS AND CERTIFICATES. WE WILL CONTINUE TO ADVOCATE THAT EUROPE, IN TURN, APPLY NATIONAL TREATMENT TO U.S. PRODUCT TESTING AND CERTIFICATION.

HOWEVER, MR. CHAIRMAN, U.S. AS WELL AS EUROPEAN MANUFACTURERS DESERVE MORE COHERENCE AND UNIFORMITY IN THE UNITED STATES REGULATORY SYSTEM FOR PRODUCT APPROVALS AND ACCEPTANCES. DIFFERENCES OF REQUIREMENTS AT THE FEDERAL AND LOCAL LEVEL THROUGHOUT THE U.S. MARKET ARE VERY COSTLY - REQUIRING MULTIPLE TESTS AND CERTIFICATIONS AND MULTIPLE PRODUCTION RUNS. THERE IS A NEED TO EXAMINE HOW THESE DIFFERING U.S. SYSTEMS UNDERCUT THE COMPETITIVENESS OF U.S. INDUSTRY IN THE U.S. MARKET AS WELL AS IN INTERNATIONAL MARKET.

THERE IS ALSO REASON TO LOOK AT THE COHERENCE OF PROGRAMS IN THE U.S. FEDERAL GOVERNMENT SECTOR. THE CURRENT SYSTEM HAS A VARIETY OF ACCEPTANCE PROGRAMS THAT ADMIT TO A VARIETY OF DIFFERING TESTING AND CERTIFICATION REQUIREMENTS INVOLVING A MIX OF OVERLAPPING U.S. AND INTERNATIONAL STANDARDS. THIS CREATES THE NEED FOR MULTIPLE CAPABILITIES THROUGHOUT THE ECONOMY WHICH MAY PROVE, UPON EXAMINATION, TO BE UNNECESSARILY COSTLY TO U.S. BUSINESS. FOR EXAMPLE, A MORE UNIFORM AND COHERENT APPROACH TO U.S. FEDERAL GOVERNMENT RELIANCE ON ONE CONSISTENT SET OF STANDARDS AND A UNIFIED ACCREDITATION PROGRAM FOR PRODUCTS REGULATED BY THE FEDERAL GOVERNMENT MAY BE A VERY POSITIVE CONTRIBUTION TO U.S. COMPETITIVENESS.

MR. CHAIRMAN, AS I INDICATED WE FOUND A VERY GREAT RELIANCE IN EUROPE ON QUALITY SYSTEMS INSPECTIONS AND THEIR RELIANCE ON THE ISO 9000 SERIES STANDARDS FOR QUALITY SYSTEMS. THIS WILL BECOME THE BASIS FOR INTERNATIONAL TRADE WITH THE EC IN CONSTRUCTION PRODUCTS, MEDICAL DEVICES, PERSONAL PROTECTIVE EQUIPMENT AND TELECOMMUNICATIONS PRODUCTS -- JUST TO NAME A FEW. MR. CHAIRMAN, I AM CONCERNED THAT WE HAVE GIVEN SCANT ATTENTION IN THE UNITED STATES TO THE CONSISTENCY AND STRENGTH OF OUR QUALITY ASSURANCE AND QUALITY ACCREDITATION SYSTEM. QUALITY ASSURANCE IS GOING TO BE VERY IMPORTANT AND WE NEED TO DEVELOP A PROGRAM IN THE UNITED STATES THAT RESPONDS DIRECTLY TO THIS NEED.

MR. CHAIRMAN, I COMMEND THIS COMMITTEE FOR CONDUCTING HEARINGS ON THIS VERY IMPORTANT SUBJECT WHICH IS KEY TO U.S. COMPETITIVENESS. THE DEPARTMENT INTENDS TO INITIATE EXTENSIVE CONSULTATIONS WITH INDUSTRY SECTORS AFFECTED BY THE EUROPEAN COMMUNITY PROGRAMS WHICH WILL COMPLEMENT THE WORKSHOPS THAT UNDER SECRETARY WHITE ANNOUNCED LAST WEEK. THE GOAL OF THESE INDUSTRY CONSULTATIONS IS TO DEVELOP THE APPROPRIATE U.S. POSITION TOWARD THE EC'S 1992 PROGRAM AND ADVANCE OUR COMMERCIAL INTERESTS. I WILL BE PLEASED TO WORK WITH THIS COMMITTEE AND YOUR STAFF TO SEE THAT THIS GOAL IS ACHIEVED.

IN CLOSING, MR. CHAIRMAN, I WANT TO THANK THE COMMITTEE FOR THE OPPORTUNITY TO PRESENT THESE VIEWS ON THIS VERY IMPORTANT ISSUE AND LOOK FORWARD TO WORKING WITH THE COMMITTEE AS THE ADMINISTRATION PROCEEDS TO DEAL WITH MARKET ACCESS AND ALL OTHER ISSUES RELATED TO THE EC PROPOSALS ON TESTING AND CERTIFICATION.

Mr. **Valentine**. Mr. Kammer.

Mr. **Kammer**. Good morning, Mr. Valentine. Good morning, Mr. Boehlert.

Mr. **Valentine**. Good morning.

Mr. **Boehlert**. Good morning.

Mr. **Kammer**. Today I'm here to talk about conformity assessment. Standardization is a two-part process. The first part is the development of the standard, and usually in a document, and then the second part is the application of that document to the real world. It is the application of the standard that actually gives the document meaning, and one of the most important applications for standards is in the area of conformity testing.

Conformity assessment is the process by which one satisfies oneself that a product meets the requirements of a standard. Conformity assessment may include testing, certification, laboratory accreditation, and/or quality assurance registration. Conformity assessment may involve only self-certification, or it could involve testing by an outsider, a third party. Conformity assessment can be a simple process or it can be an exceptionally complex process.

Organizations which conduct conformity assessment may be governmental or they may be private sector. The assessment process itself may be voluntary, it may be mandatory, or it may be mandatory only under certain conditions.

In the United States, the actual assessment process may be conducted by a private sector body on behalf of a state agency, the assessment may be conducted by a state agency on behalf of the Federal Government, and there are examples of shared responsibility, and more than one approach may actually exist for the same product area in the United States.

Basically, in the United States, conformity assessment is splendid in its diversity—and that's probably the most positive description I can put on that.

Promoting the mutual recognition of conformity assessment procedures and schemes between and among countries can do much to eliminate the barriers to free trade. The European Community has recognized this fact and has devoted considerable resources towards establishing uniform procedures for demonstrating compliance to what they call essential requirements contained in their directives. Such procedures will allow a regulated product which is tested in one EC country to be sold in any EC country after that without the need for retesting.

Conformity assessment is not an area we can afford in the United States to ignore if we wish to be a competent and effective player in the international market. Bilateral and multilateral solutions and strategies, however, will not be easy to formulate. NIST has for some time been collecting and analyzing information to help identify who in the United States conducts conformity assessment activities and how such activities are conducted.

Because the area is so complex, the issues and the problems that the United States will face in trying to develop a coordinated U.S. position will be very difficult to resolve. Government-to-government exchanges designed to work out mutually acceptable agreements, which recognize all or some of each other's assessment procedures, are likely to be hampered by the complexity of the U.S. system.

Differences in the way the products are regulated will also need to be addressed. For instance, products that are regulated in the United States may or may not be regulated in other countries. Products which we have chosen not to regulate may be regulated in other countries.

Strategies to address these and the other issues that surround conformity assessment will likely have to be formulated on an industry-by-industry basis. The needs and problems faced by each industry vary greatly, and one approach is not likely to be suitable for all industries.

One possible step to begin the effort of developing and effective U.S. strategy is to hold meetings on an industry-by-industry basis to try and reach bilateral and multilateral U.S. negotiating positions. These meetings would allow all interested parties—the manufacturers, the buyers, the certifiers, and the government at all levels, state and Federal—to discuss their needs and problems, the needs of the industry, as well as the specific trade problems facing that industry in today's global marketplace.

NIST is actively considering holding such a series of meetings and actually looks forward to making the attempt to reach some consensus in this area.

Thank you very much.

[The prepared statement of Raymond G. Kammer follows:]

NIST
UNITED STATES
DEPARTMENT OF COMMERCE
NATIONAL INSTITUTE OF STANDARDS
AND TECHNOLOGY

TESTIMONY OF RAYMOND G. KAMMER, DEPUTY DIRECTOR
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
BEFORE THE SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY
HOUSE COMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY
ON INTERNATIONAL TESTING AND CERTIFICATION

JUNE 26, 1990

Mr. Chairman and Members of the Committee. My name is Ray Kammer. I am the Deputy Director of the National Institute of Standards and Technology (NIST). Under Secretary White focused his remarks at the hearing last week primarily on standards development, I will direct my remarks today to the area of conformity assessment.

We need to recognize that standardization is a two part process. The first part being the development of the standard document, and the second being the application of that document in the "real world." It is the application of the standard that gives the document meaning, and one of the most important applications for standards is in the area of conformity assessment. Conformity assessment is the process by which one satisfies oneself that a product meets the requirements of a standard -- in other words, that the product will be long enough, big enough, strong enough, or have whatever other qualities and characteristics one deems essential.

The conformity assessment process may encompass many diverse activities such as testing, certification, laboratory accreditation, and quality assurance registration. Conformity assessment may involve only self-certification, which is a statement by a manufacturer that his product meets the requirements of a standard. Or it may involve an outside or third party who is responsible for determining that the product complies with whatever requirements have been imposed under the assessment scheme.

Conformity assessment can be a simple process, such as looking at a product and giving it an OK. Or it can be a complex scheme involving a complete review of the manufacturing process, registration of the manufacturer's quality assessment system, extensive product testing in an accredited lab, and the imposition of extensive product labeling and marking requirements.

Organizations which conduct conformity assessment may be governmental or private sector. Within the government, the assessment may be conducted at the federal, state or local level. In the private sector, the assessor might be a trade association, a professional society, an independent laboratory, or some other party.

The assessment process itself may be voluntary, mandatory, or mandatory only under certain conditions -- such as if the product will be shipped interstate or if the product will be sold to the federal government.

In the United States, the actual assessment process may be conducted by a private sector body on behalf of a state agency, an occurrence common in the area of electrical equipment. Or an assessment may be conducted by a state agency on behalf of a federal agency, as in the assessment of drinking water. There are many different examples of such shared responsibility, and more than one type of approach may exist for the same product area.
If responsibility for the assessment is shared with another body, that body may or may not impose additional requirements on the product. For example, most states inspect meat products for the U.S. Department of Agriculture. Some states, however, impose additional requirements on those meat products over and above those of the USDA.

Little wonder that we receive complaints from other countries that our system is difficult if not impossible to understand!

But understanding is essential because the impact of conformity assessment activities can be enormous. In the past, such activities have had a major influence on all aspects of American life. Today, while such activities continue to pervade our lives domestically, they are also assuming increased importance internationally. In the 1990's, we will likely see the continued emergence of a global economy. The United States must formulate strategies to deal with issues, such as conformity assessment, which are likely to significantly impact on that economy.

Promoting the mutual recognition of conformity assessment procedures and schemes between and among countries can do much to eliminate barriers to free trade. The European Community has recognized this fact and has devoted considerable resources towards establishing uniform procedures for demonstrating compliance to the "essential requirements" contained in their Directives. Such procedures will allow a regulated product which is tested in one EC country to be sold in any other EC country without the need for automatic retesting. Government and industry alike have repeatedly recognized the impact that conformity assessment procedures, such as these, will have on the United States' ability to continue to compete effectively.

We have also seen the importance of conformity assessment issues in our efforts to implement the United States/Canada Free Trade Agreement. New conformity assessment issues and problems will arise and need to be addressed as we work to establish a free trade agreement with Mexico. Few are likely to forget the problems and difficulties the United States has faced with Japan in resolving conformity assessment issues for products ranging from autos to baseball bats. In the negotiations underway to revise the General Agreement on Tariffs and Trade's Standards Code, issues surrounding conformity assessment and its impact on trade have also repeatedly been raised.

Conformity assessment is no longer an area we can afford to ignore if the United States is to continue to be a competent player in the international market. Bilateral and multilateral solutions and strategies, however, will not be easy to formulate. NIST has for some time been collecting and analyzing information to help identify who in the United States conducts conformity assessment activities and how such activities are conducted. Outside of this information collection effort, however, there have been few attempts either by government or the private sector to understand -- let alone coordinate -- such activities in the United States. What limited efforts have been undertaken, have generally been extremely narrow in scope.

Because the area is so complex, the issues and problems the United States will face in trying to develop a coordinated U.S position will be difficult ones to resolve. Government-to-government exchanges designed to work out mutually acceptable agreements which recognize all or some of each other's assessment procedures are likely to be hampered because of the complexity of the U.S. system and its lack of coordination. Differences in the way products are regulated will also need to be addressed. For example, products regulated in the United States may or may not be regulated by other governments. Products, which we have chosen not to regulate, may nonetheless be subject to mandatory conformity assessment procedures in other countries. The nature and number of the assessment procedures used and the requirements imposed on specific products will also vary greatly among countries.

Strategies to address these and other issues surrounding conformity assessment will have to be formulated on an industry-by-industry basis. The needs and problems faced by each industry vary greatly, and one approach is not likely to be suitable for all industries. The need for and advantages to U.S. manufacturers of bilateral or multilateral mutual recognition arrangements will also vary by industry and must be considered before formulating a strategy for that industry.

One possible step to begin the effort of developing an effective U.S. strategy would be to hold meetings on an industry-by-industry basis to formulate bilateral and multilateral U.S. negotiating positions. These meetings would allow all interested parties -- manufacturers, buyers, certifiers, and government at all levels -- to discuss their needs and problems, the needs of the industry, as well as the specific trade problems facing that industry in today's global marketplace. Such an effort would be invaluable in formulating a strong, cohesive U.S. negotiating position on matters related to the establishment of any mutual conformity assessment recognition agreements.

In conclusion, I would like to say that NIST would be pleased to conduct such meetings involving appropriate private sector interests and government agencies. Thank you. I will be happy to answer any questions you may have.

RAYMOND G. KAMMER

Acting Director
National Institute of Standards and Technology (NIST)
(Formerly National Bureau of Standards (NBS)
United States Department of Commerce

Ray Kammer is Deputy Director of NIST. He is currently Acting Director as well. NIST is the Nation's central laboratory for measurement and standards research in support of U.S. industrial needs. Kammer manages the NIST staff of close to 3100 physicists, chemists, mathematicians, engineers, and support personnel.

A graduate of the University of Maryland, Kammer joined NIST in 1969 as a technical program analyst. Over the following decade he served the agency and the U.S. Department of Commerce in a succession of offices concerned with budgetary and program analysis; planning; and personnel management. In 1980, Kammer was appointed Deputy Director of NIST.

In addition, Kammer has served as chairman of several important evaluation committees for the Department of Commerce, including reviews of satellite systems for weather monitoring and the U.S. LANDSAT program, and the next generation of weather radars used by the U.S. government. He is now serving a three-year term on the Board of Directors of ASTM, a major international organization for the development of voluntary standards for materials, products, systems and services.

His awards include both the Gold and Silver medals of the Department of Commerce, given for meritorious service to the Department and the nation, the William A. Jump Award for Exceptional Achievement in Public Administration, the Federal Government Meritorious Executive Award, and the Roger W. Jones Award for Executive Leadership.

February 1989

Mr. Valentine. Thank you, sir.

Mr. Deusterberg, in your testimony, having to do with your recent trip to Europe with regard to mutual recognition and testing and certification requirements, you made a point of the idea of U.S. desire for national treatment as opposed to the European Community's desire to adhere to the idea of a balanced commercial situation, could you amplify that a bit? Why is EC so insistent on their view, and how do we plan to deal with this?

Mr. Duesterberg. Well, let me—As I mentioned in my testimony, EC's concept of a balanced situation is somewhat fluid, and I don't think that they have a totally clear idea of what they mean by it.

A bit of history. When the EC started thinking about a coherent testing and certification system, their plans did not seem to include much participation at all by labs and certification organizations outside of the Community. They have since modified their position quite substantially and have admitted the possibility of U.S. testers and certifiers and, indeed, U.S. companies themselves, to participate in the system in a variety of ways.

Again, we're going to have to see how their thinking evolves further, because they haven't nailed it all down yet. But it does appear that they're going to allow significant participation in a number of ways.

What we have asked for is basically national treatment, that they not treat the laboratory outside the Community any differently than they would a laboratory within the Community. And they seem to be holding out a distinction that is hard for us to accept, and that is that their philosophy is that they are creating a unified market of 320 million people, access to which is something that is new, and it will be a great benefit for the U.S. manufacturer.

I think it's hard to argue with the point that they are creating a new unified market. We hope that their testing and certification system will provide the access that we think it will. But the point that we've made time and time again to them is that we already provide access to the U.S. market. The European labs are free to negotiate mutual recognition agreements with any of the various components of the U.S. testing system, and there are no impediments that we can think of to their participation in the system. Therefore, we find it difficult to contemplate what we would negotiate on on that basis.

So our attempt in a various series of discussions has been to convince them that the U.S. system is open and that they ought to provide access on a nondiscriminatory, national treatment basis. The only thing we can do is to keep working with them to try to achieve that. We've had these series of discussions and the Community has moved quite significantly in its thinking over the last six to nine months.

Mr. Valentine. In your statement you indicate that both U.S. and European, overseas manufacturers, deserve more coherence and uniformity in the U.S. regulatory system. Could you amplify that briefly?

Mr. Duesterberg. Well, I don't want to overdramatize this point. The one thing I would emphasize in this whole discussion is that, even though the U.S. system is diverse and somewhat decentralized, it has stood the test of time and it has worked, and it provides a service to the manufacturing community and to the consumer that has worked well. On the other side, the Europeans are creating a system de novo which is going to have to be tested by the marketplace. The consumer is going to have to come to accept whatever system they put in place and whatever marks of conformity they put into place.

But what I would say is that it is clear that, as I think Congressman Boehlert mentioned in his opening statement, the world economy is becoming more internationalized. Markets are becoming larger, and the European Community is creating a unified market. A manufacturer that has to produce to a variety of standards, either within the United States or internationally, sometimes is not able to achieve the economies of scale that he might like. If they have to test to different standards, or they have to provide different test results for different jurisdictions, that also is perhaps not as efficient a system as we would like.

I don't think we're going to be able to impose a system from above on the United States, or it's not going to gain the acceptance from the manufacturing community, it's not going to gain the acceptance from the consumer, simply because we try to do something by government fiat. I think what we need to do is think about ways in which we can rationalize the system as it exists, move it towards somewhat more coherence. I think just the fact that we're here discussing this today, that we've discussed this in the context of what Europe is doing, I think is a positive step.

Mr. Valentine. One of the witnesses who will testify later, Mr. Leonard Frier, has pointed out that most countries in the world have some sort of a national quality mark. Do we need the same sort of thing?

Mr. Duesterberg. Again I would emphasize that the European Community is, in Brussels, at least, has conceived of a unified quality mark. They have to gain acceptance of that mark in the marketplace. My sense is that it will take them a long period of time to do that.

I think the panel which follows me, which is much more experienced in expertise, will attest to that as well. But I don't want to underestimate what we have in the United States. We have marks in the United States that have fairly wide acceptance. You're going to hear from Underwriters Laboratories that this mark has generally broad acceptance, not only in the United States but in the international community as well.

At this point in time I think it's something we need to look at, but I would not come right out and endorse any single national quality mark at this point in time.

Mr. Valentine. Mr. Kammer, given NIST's extensive experience in testing and certification, what is your opinion as to the best approach to obtain a focal point for conformity assessment in the United States? Should it be a government or a private organization, or a combination of both?

Mr. Kammer. Sir, in my view, a combination of both is the proper direction I think to work towards. Clearly, as Assistant Secretary Deusterberg was describing earlier, there's a role for government negotiation and there will probably be government-to-government agreements in some areas.

But we already have a lot of very successful and effective elements of certification system in the United States. The ASME, I think, testified before you all last week, and they have the boiler and pressure vessel code which is accepted all over the world. And UL, of course, their product testing is accepted internationally, too. One would want to be very cautious not to detract from the parts of the system that work exceptionally well already.

Mr. VALENTINE. Could the National Voluntary Laboratory Accreditation Program, could that serve as a framework for a comprehensive accreditation system, and how is that accepted by foreign countries?

Mr. KAMMER. Well, it's—for the people that want to use it now, it, indeed, does provide a comprehensive accreditation. It covers all of the needs that people on a voluntary basis wish to avail themselves of.

And it's enjoyed pretty good acceptance, I would say, in the international arena. NVLAP is the U.S. delegation head for something called ILAC, which is the International Laboratory Accreditation Conference. And we have bi-national agreements with a number of countries—the United Kingdom, Canada, New Zealand, Australia. Indeed, there are a lot of Federal laboratories that have been interested in being accredited by NVLAP, and in the cases where they have applied and met the requirements, they have been accredited. So I'd say pretty good acceptance.

Mr. VALENTINE. One more question and I will yield to Mr. Boehlert.

Has NIST reviewed the effectiveness of current private accreditation programs in terms of ensuring that the labs are qualified to test and to certify the products?

Mr. KAMMER. We really haven't. I know of no entity that has the responsibility at the moment for kind of testing the accreditors, if you will, or accrediting the accreditors.

In legislation that's been considered by this committee on fasteners, and I think is under active consideration in the Senate now, in that limited area NIST would be given responsibility for making a judgment on whether or not accreditors were successful, and that would be our first experience with that.

Mr. VALENTINE. Mr. Boehlert.

Mr. BOEHLERT. Mr. Deusterberg, do you think Europeans are using conformity assessment as sort of a monumental, nontariff trade barrier?

Mr. DUESTERBERG. Congressman, I've got to say that I don't.

Mr. BOEHLERT. I hope you're right.

Mr. DUESTERBERG. Well, I hope I'm right, too.

We have a ways to go, as I tried to point out, with the Europeans setting up their system. Their stated desire is clearly not to make it an impediment to trade. But, as I also tried to point out, they also don't want to give access to the system unless they, in their own minds, get something in return. They have a lot to get from the United States. And one of the things they have to get from us is some recognition of the legitimacy of their system.

We have a system in place, diverse as it may be, that nonetheless works and provides access to the U.S. market, which is still the biggest market in the world. And because of that, I think that they would be quite willing to work with us and not—especially working with us as opposed to some other countries, perhaps—set up a system that would provide an impediment, because we not only have a market that we could use against them, but we have a system which provides legitimacy which they're going to need. They're not going to be able to just, by fiat, set up this new coherent system and gain widespread acceptance in Europe and abroad.

Mr. **Boehlert**. You know, stated desires and covert attempts sometimes are entirely different. I've heard, for example—I don't know if it's fact or fiction—that in Germany, U.S. typewriters, U.S.-made typewriters, cannot be exported to Germany because they don't meet the standard for size of type.

Mr. Kammer, have you ever heard that story?

Mr. **Kammer**. No, sir, I haven't.

Mr. **Boehlert**. Do you want me to flush it out? I can flush that out for you and get you some details on it.

Coincidentally, I do have a typewriter manufacturer in my district, so I have more than a casual interest.

Mr. **Duesterberg**. Congressman, let me—if I can comment on that.

Mr. **Boehlert**. Sure.

Mr. **Duesterberg**. I mean, that's a standards question that is faced by Smith-Corona. I think it's been under discussion for some time and has something to do with the disposition of the keyboard. I don't understand it all that well. But it's not something that is new; it's something that's specific to Germany. The Germans are eventually going to have to harmonize their standard with European-wide standards.

To me, that case is an example of attesting to the fact we've just got to be vigilant. I don't think the Germans conceived of the standard that they put into place as anything more than one of putting into place a good standard, of getting the keys in the right place in this case. They have slightly different ideas on that than we do on this side of the Atlantic.

Mr. **Boehlert**. So you don't see any Machiavellian plot?

Mr. **Duesterberg**. Well, you see, I think we've got to work—we've got to pay a lot more attention than we have in the past to their efforts like that. I think we have shown where we can point out to them where it's going to create an impediment to trade. They're willing to listen to us. We've had a number of cases where we've been able to work with them on standards cases. They will take a—

Mr. **Boehlert**. To a successful resolution on the part of our interested parties?

Mr. **Duesterberg**. I believe so, yes.

Mr. **Boehlert**. So you wouldn't put them in the same category as our Japanese friends who are so creative at directing these nontariff trade barriers?

Mr. **Duesterberg**. I'm not going to say that in every case there's not some thought in the back of their mind, but I think in most cases they are willing to work with us because we have a large market and they don't want to create any problems with us. And as I said earlier, especially in the testing and certification area, they've got to get legitimacy for their new system, and we can provide that to a certain extent. So I think, you know, we can work with them on the margins.

Mr. **Boehlert**. Are you familiar with that Smith-Corona case?

Mr. **Duesterberg**. I'm somewhat familiar with it. I am fortunate to have with me an expert in this area from my staff, who I think, if you're interested in pursuing it, could probably give you the details.

Mr. **Boehlert**. Well, I would appreciate something in writing following this up, sort of give me a heads up on where we are in this and your view from the Department's—

Mr. **Duesterberg**. We'll be happy to provide that to you, Congressman.

Mr. **Boehlert**. All right.

Let me ask you another question. Other than preempting state rules, do you foresee any need for changes in this U.S. splendid and diverse conformity assessment procedures?

Mr. **Duesterberg**. I'd follow up on something Mr. Kammer said. I'm not sure I'm going to advocate preempting state rules.

What I think we've got to do is, especially with the attention that's being paid to quality, and the basic fact that we need to emphasize competitiveness and quality wherever we can, I think we've got to pay attention to an accreditation system which attests to quality manufacturing systems and quality in testing laboratories. So it's more in the area of uniformity of standards with regard to quality assurance that I think we need to give some attention to perhaps national standards.

Mr. **Boehlert**. Nothing more, Mr. Chairman.

Mr. **Valentine**. Doctor, how do we plan to ensure compatibility of safety, health and environmental requirements between the United States and our foreign trading partners?

Mr. **Duesterberg**. Well, I'm not sure that our job is to assure a hundred percent compatibility. Our job is to assure that the safety requirements which we think we need here, and the safety requirements which others may need, do not provide insuperable barriers to trade. We work as much as we can to emphasize international standards, but I think we've also got to recognize that different governments, different cultures, are going to demand different sorts of safety protections on different sorts of products. So what we need to do is make sure that we don't use those—or other countries don't use those differing requirements to keep products from other countries out. That is, we need to make sure that, for instance, the Europeans don't use product safety standards to make it impossible for the U.S. manufacturers to sell in their markets, or for the U.S. laboratories to test products that are going to be sold in those markets.

Mr. **Valentine**. Thank you, sir—thank both of you. We could probably run along here for a while longer, but then, in view of my statement when we started these proceedings, I think we had better stop here now because of Mr. Mandela's speech to the Congress. So if you will just be at ease, we will—I just have to make an educated guess at this. I think we would perhaps be finished with this ceremony and be able to get back about 15 minutes after 12:00. So we will plan on greeting panel number two at that time.

We will be in recess.

[Recess.]

Mr. VALENTINE. I'm sorry I'm a little bit late, folks. We'll get back into the work of the subcommittee with panel two, Mr. Wilgis, Mr. Bhatia, Mr. Fier and Mr. Locke. Welcome, gentlemen.

The second panel consists of Mr. Herbert Wilgis, American Council of Independent Laboratories; Mr. S. Joseph Bhatia, Vice President, Governmental Affairs, Underwriters Laboratories, Inc.; Mr. Leonard Frier, President, MET Electric Testing Company, Inc; and Mr. John Locke, President, American Association for Laboratory Accreditation.

I apologize to you again for the delay, at least some of which was unavoidable. We welcome you here. Your prepared statements will appear in the record as presented to us, and I invite you to summarize or otherwise proceed as you deem appropriate. We're glad to have you.

Mr. Wilgis?

STATEMENTS OF HERBERT E. WILGIS, JR., PRESIDENT, PENNIMAN & BROWNE, INC., APPEARING ON BEHALF OF THE AMERICAN COUNCIL OF INDEPENDENT LABORATORIES, ACCOMPANIED BY MILTON BUSH, DIRECTOR OF PUBLIC AFFAIRS; S. JOSEPH BHATIA, VICE PRESIDENT, GOVERNMENTAL AFFAIRS, UNDERWRITERS LABORATORIES, INC.; LEONARD FRIER, PRESIDENT, MET ELECTRICAL TESTING COMPANY, INC.; AND JOHN W. LOCKE, PRESIDENT, AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION (A2LA)

Mr. WILGIS. Thank you very much, Mr. Chairman. Good afternoon.

My name is Herb Wilgis. I am President of a small business, Penniman & Browne, Inc., a commercial testing laboratory in Baltimore, MD. We offer engineering, chemical, metallurigical and environmental testing, as well as analytical and consulting services.

Our company is a member of the American Council of Independent Laboratories, also known as ACIL. I am accompanied by Milton Bush, Director of Public Affairs of ACIL. Mr. Bush has just returned from Europe where he had several meetings with the European Commission.

I am pleased to have the opportunity to speak on behalf of ACIL today about the testing and certification process in the United States and the role it plays in international markets. The subcommittee's hearings on this subject are particularly timely in light of the European Community's effort to create a single market in 1992.

I will summarize ACIL's prepared statement. However, I would first ask the Chairman that my entire statement be placed in the record.

Mr. VALENTINE. Without objection.

Mr. WILGIS. ACIL is the trade association that represents independent, commercial laboratories engaged in testing, analysis, investigation, sampling, research and development, and/or consultation for the public. We represent an industry of over 4,000 laboratories contributing an estimated $11 billion annually to the Nation's economy. The testing industry is, we believe, unique, important and crucial in maintaining our Nation's ability to compete in the international marketplace.

Our remarks must be made from the perspective of the laboratories which try to and, to an increasing extent, must meet the varying needs of their clients, clients which include private companies which are concerned about quality, agencies of local, state and Federal Governments, and clients which must meet the requirements of Government agencies.

To summarize the condition of our present system, it is not working well, and for the following reasons:

First, because a laboratory must obtain multiple certifications and accreditations, it is not unusual, for example, for one laboratory to need to be certified by more than one agency of the Federal Government, every state government in it's market area, several industrial groups, and even more individual clients with their particular quality assurance programs.

Second is the cost of these multiple accreditations. Each one costs from one to several thousand dollars at a minimum, which when multiplied adds up to a serious cost for a small business. But the real cost to a laboratory is another multiple of the fee it pays to the accreditor when you calculate the time it takes management to prepare for an accreditation, technicians to perform test kits, and supervisors to implement standards.

Regretfully, there is also a third feature: the uncoordinated nature of our present system leaves gaps, the possibility for misrepresentation of actual certifications, confusion, and real problems for clients who try to ascertain if a laboratory is certified or if a certification exists for the particular test or analysis the client requires. Our uncoordinated and undisciplined approach cannot interface effectively within international systems.

But before I discuss the problems we have in the international market, I want to underline one feature which is not a problem. As you know, our present system for certification and accreditation is a mixture of the private sector and the Government which allows us to marry expertise and experience in the private sector with expertise and authority in the Government. In most, but not all, other countries, certification of testing laboratories is carried out by the government.

You may receive comments, Mr. Chairman, that this is a problem, that the United States must place responsibility for accreditation exclusively in the Government. We respectfully disagree. Many things, partially or completely in the private sector in the United States, are more typically governmental functions in other nations. The telephone system is one obvious example; airlines, railroads, medical care are others. Testing, certification and accreditation are similar examples.

We commend the subcommittee's focus on the European Community, or EC. We have described in detail in our written statement our perception of how the EC system will operate in 1992. I would like to summarize briefly some of our main points.

The subcommittee is correct to point out that the U.S. testing laboratories cannot become notified bodies at present for regulated products. This situation, by itself, places U.S. testing laboratories at a disadvantage because, in contrast, the U.S. system is open to foreign participation. One example, electromagnetic compatibility testing, known as EMC, is regulated in the U.S. at the Federal level by the FCC and NIST through NVLAP. Eighteen foreign laboratories, many of them European, are certified to test for the U.S. market. It is true that EC policy permits U.S. testing laboratories to receive subcontracts from EC notified bodies, but there is no competitive advantage for EC notified bodies to do this. It is also true that a U.S. testing laboratory could establish a subsidiary in an EC country and seek notified body status for it. But this is clearly an artificial incentive to invest in the EC. It is also too expensive for U.S. testing laboratories to undertake. Thus, in testing regulated products, U.S. laboratories are placed at a severe disadvantage.

The situation with respect to products that are unregulated in the U.S. but regulated in the EC is even worse. Construction products is one example. They are regulated in the EC. In the U.S., some are regulated, but those that are typically are regulated at the state, local or municipal level in specific codes, especially in the area of safety. If the EC is willing to negotiate in this area, the question arises who would negotiate for the U.S.

In the case of services provided by testing laboratories, the situation is equally bleak. Here we refer to increasingly important areas such as environmental protection, which is regulated in both the U.S. and EC, but to different standards and using different test methodologies. The EC has yet to address the laboratory services issue, but we believe it will adopt the same global approach principles as already adopted for product testing.

In summary, we believe there is a real threat to the U.S. testing industry and, beyond that, to the ability of U.S. industry in general, to compete in Europe and other international markets. This threat is particularly acute to small businesses. The ACIL believes that a complete reexamination of the U.S. testing certification and accreditation industry needs to be undertaken, squared with developments internationally, and performed by a congressionally-chartered national commission.

A system that ACIL could support would include, but would not be limited to, some of the following elements: principally private sector; subject to congressional oversight; open and transparent; subject to administrative procedures required by law; nonpreemptive of existing Federal programs unless requested by the affected agency; and equipped with sufficient checks and balances. Functions of such a system would include, but would not be limited to, one, the reciprocal acceptance of test data internationally, two, the recognition of U.S. laboratory accreditation schemes, and three, the negotiation of U.S. laboratory access internationally.

Thank you, Mr. Chairman, for the opportunity to express our views. We would be glad to respond to your questions.

[The prepared statement of Herbert E. Wilgis follows:]

TESTIMONY OF

HERBERT WILGIS

ON BEHALF OF THE

AMERICAN COUNCIL OF INDEPENDENT LABORATORIES

BEFORE

THE SUBCOMMITTEE ON SCIENCE, RESEARCH & TECHNOLOGY

COMMITTEE ON SCIENCE, SPACE & TECHNOLOGY

U.S. HOUSE OF REPRESENTATIVES

JUNE 26, 1990

Good morning. My name is Herb Wilgis. I am President of a small business, Penniman & Browne, Inc: a commercial laboratory in Baltimore, Maryland. We offer engineering, chemical, metallurgical and environmental testing, analytical and consulting services. Our company is a member of the American Council of Independent Laboratories, also known as ACIL. I am accompanied by Milton Bush, Director of Public Affairs of ACIL. I am pleased to have the opportunity to speak on behalf of ACIL today, about the testing and certification process in the United States and the role it plays in international markets. The Committee's hearings on the subject are particularly timely in light of the European Community's effort to create a single market in 1992.

ACIL is the trade association that represents independent, commercial laboratories engaged in testing, analysis, investigation, sampling, research, development and/or consultation for the public in the fields of engineering and the sciences. ACIL's membership is broad-based representing all laboratory disciplines except clinical. ACIL represents an industry of over 4000 laboratories contributing an estimated $11 billion annually to the nation's economy - a number that is growing as American consumers demand a safer and greater quality of life. The testing industry is, we also believe, unique, important, and crucial in maintaining our nation's ability to compete in the international marketplace.

Our remarks must be made from the perspective of laboratories which try to -- and to an increasing extent must -- meet the varying needs of clients, clients which include private companies which are concerned about quality, agencies of local, state and federal governments; and clients which must meet the requirements of government agencies. To summarize the condition of our present system: it is not working well, and for the following reasons.

First, a laboratory must obtain multiple certifications and accreditations. It is not unusual, for example, for one laboratory to need to be certified by more than one agency of the Federal Government, very state government in its market area, several industrial groups, and even more individual clients with their particular quality assurance programs.

Second, is the cost of these multiple accrediations. Each one costs from one to several thousand dollars at a minimum, which, when multiplied, adds up to a serious cost for a small business. But the real cost to a laboratory is another multiple of the fee it pays to an accreditor when you calculate the time it takes management to prepare for an accreditation, technicians to perform test kits, and supervisors to implement standards.

Regretfully, there is also a third feature: the uncoordinated nature of our present system leaves gaps, the possibility for misrepresentation of actual certifications, confusion, and real problems for clients who try to ascertain if a laboratory is certified or even if a certification exists for the particular test or analysis the client requires.

Our uncoordinated and undisciplined approach cannot interface effectively with international systems. But before I discuss the problems we have in the international market, I want to underline one feature which is not a problem. As you know, our present system for certification and accreditation is a mixture of the private sector and the government, which allows us to marry expertise and experience in the private sector with expertise and authority in the government. In most, but not all, other countries certification of testing laboratories is carried out by the government. You may receive comments that this is a problem; that the United States must place responsibility for accreditation exclusively in the government. We respectfully disagree. Many things partially or completely in the private sector in the United States are more typically governmental functions in other nations. The telephone system is one obvious example. Airlines, railroads and medical care are others. Testing, certification and accreditation are similar examples.

Peter Drucker in his latest book, The New Realities, analyzes the new limits and functions of government and the changing demands of political leadership juxtaposed with the transnational economy and the paradoxes of economic development. Drucker does not offer solutions or focus on what to do tomorrow; he states what he believes we must do today in contemplation of tomorrow.

Drucker's insights are vividly on display today as the government is groping to find its role in international testing and certification activities. ACIL believes it can assist in this endeavor by first providing a brief historical background on efforts by the U.S. government to organize and coordinate testing, certification and accreditation activities in the United States; by describing the present state of these activities in the U.S. and the European Community; and finally (using Drucker's method), by proposing a solution today that may offer competitive assistance to the U.S. testing industry in light of worldwide regional consolidation efforts tomorrow.

The first major effort on behalf of the government organize and coordinate testing, certification and laboratory accreditation in the United States began in the mid-1970's and culminated in the creation of the U.S. Department of Commerce National Voluntary Laboratory Accreditation Program, still known as NVLAP. ACIL was an active participant in the creation of this program, as was ASTM, the National Conference of States on Building Codes and Standards, and many of the other affiliated organizations mentioned earlier.

Prior to this and since 1929, the National Bureau of Standards participated with Federal and State agencies and private interests in establishing evaluation criteria for testing laboratories and in providing on-site examinations, proficiency test samples, calibrated standards and materials. Several hundred laboratories working in areas such as concrete, cement, asphalt, paper, fiberboard, color and appearance, clinical and forensic testing made use of these services. However in 1969, ASTM requested NBS and others to participate in establishing a testing agency inspection service that would provide testing laboratory examination services over a broad range of product areas wherever needs developed. In 1970 a conference was convened by NBS to consider the idea of a national voluntary laboratory accreditation system. An ad hoc committee, designated by the conference, developed a concept of such a system but contained no plan for its implementation. Alternatives that were being considered were: establishment by incorporation in the private sector; establishment by legislation; and establishment by a government agency under existing authority.

In 1973, the Secretary of Commerce initiated action to evaluate the merits of establishing a quasi-public national laboratory accreditation board. Over the course of three years oral and written comments were solicited, the culmination of which was the establishment of NVLAP in 1976.

Currently NVLAP operates eighteen (18) accreditation programs. Viewed objectively, the implementation of only eighteen programs in fourteen years can hardly be viewed as successful. However the reasons for NVLAP's rather dismal performance has not been entirely its own doing. During the three year period when the creation of NVLAP was being considered, there was widespread interest and support for the proposed program based on classes of technology (i.e., a disciplined-based system). However, particular product sectors argued that there was no need for laboratory accreditation in their areas of interest. You will again hear the same arguments from the same sectors. However, the testing community, and this community cuts across all product sectors, still needs a techology-based system and that need is even greater today. Today, because what's driving the need for such a system today, is international in scope, not solely national considerations.

The next event in the evolution of the Federal government's interest in standards, testing and certification concerned an investigation by the Federal Trade Commission at a time when the Commission provisionally accepted consent orders in a matter involving marketing misrepresentations relating to the flammability of foam plastics used as insulation in buildings. A Federal rule was proposed, based on that directive, that would have established prohibitions and requirements for standards developers, certifiers, and persons who reference standards or certifications in the marketing of products. While the rule was subsequently withdrawn and many of the conclusions of the FTC staff report called into question, one conclusion remains valid in light of international developments. The Commission stated that "...(c)ommission enforcement of the consumer protection and competition laws in the standards and certification area would complement the efforts of other Federal agencies. Their concerns include such things as reducing the effects of standards as non-tariff trade barriers, introducing energy and cost-saving technology, protecting the public health and safety within acceptable cost levels, and facilitating lowest cost government procurement and regulation through use of private standards.

Since the Commission investigation in 1878, we have experienced Hydrolevel and Allied Tube, and many safeguards that were not present in 1978 are present today. However, we have not seen progress in the areas of concerns articulated by the Commission in the areas of non-tariff trade barriers, safety, health and the environment. And these are precisely the areas where the European Commission has seen a national role, preempting conflicting state and local requirements, and allowing the free flow of goods between and among markets.

If the Federal Trade Commission's concerns are valid today
in the context of which they were originally framed - national; then it is even more imperative that they be examined again in the context of what is occurring internationally.

The present state of testing, certification and accreditation at the Federal level is described in a March 1989 report by the General Accounting Office, requested by the Chairman, Committee on Science, Space and Technology, House of Representatives. While the purpose of study was to identify overlapping and burdensome certification and accreditation programs, (which it only found one), a cursory review reveals that there is no coodinating mechanism among government agencies: terms for accreditation vary; approaches to accreditation vary (direct versus delegation of authority to inspect or to issue certificates versus delegation of authority to accredit others); accreditation requirements vary (organizational information, QA/QC, personnel, facilities and equipment, records and recordkeeping, test reports, proficiency testing, fees, conflicts of interest and financial stability; and accreditation procedures vary (application, maintenance, and assessment).

There is one Federal program that deserves mention because of its precedent-setting nature - the OSHA Nationally

Recognized Testing Laboratory (NRTL) program. Without going into its details, the NRTL program shows promise as a means of: coordinating private sector laboratory interests; accrediting laboratories; and responding to unfair competition when a non-U.S. laboratory accreditation scheme is not open, transparent or coordinated.

Again, the nature of this report was driven by national considerations. It is still an open question whether such an uncoordinated and undisciplined approach can interface well with international developments. I will explore this in more detail in the next section dealing with developments within the European Community. The conclusion that is crystal clear (after this historical perspective and discussion of the present state of testing, certification and accreditation), however, is that the driving force in these initiatives has been national in nature. International considerations are now driving the coordination and organizational effort today. ACIL believes that testing, certification and accreditation in the United States needs to be re-examined once again, but in an international context. The need will become more apparent after a discussion of the European Community's Global Approach to Testing and Certification.

The European Community has embarked on an ambitious and thoughtful program whose goal by 1992 is to eliminate all non-tariff barriers and other impediments to commerce and create a true Common Market among the Member States of the EC and EFTA (the European Free Trade Association). Under the program of EC 1992, three major types of barriers to trade will be eliminated: physical barriers, fiscal barriers, and technical barriers. The most direct impact on the U.S. testing and certification industry will be in the area of these intra-European technical barriers to trade.

The Community's challenge was to devise a system of standards, testing and certification that would allow the free flow of products and services among the Member States, and at the same time, preserve the authority of individual Member States to maintain their own standards, testing and certification systems. Thus, the EC contracted with two regional standards bodies, CEN and CENELEC to develop "harmonized" European standards (designated as "EN's"). EN standards, in most cases, have drawn heavily from international standards of the International Standards Organization (ISO) and the International Electrotechnical Commission (IEC).

ENs establish "essential requirements" to which all products flowing among the Member States must be tested. If products conform to these "essential requirements," they cannot be barred from any Member State. Testing to these "essential requirements" will be performed by what the European Commision calls a "notified body." Conformity to these "essential requirements" will be designated by the application of the mark, CE. The CE mark thus will become a "conformity mark," not a certification mark. It will operate as a product's passport into the Member State. Individual Member States can then require additional testing; and in these cases another mark will be applied, usually the mark of the testing body.

Testing by a "notified body" will be required only in those product areas that are **regulated** by the Commission, i.e. the subject of a directive. Regulated product areas are those that involve public health, safety and the environment. The degree of risk associated with a particular product will determine the types of testing, inspection and certification that will be required by what the Commission calls the "modular approach." In the interest of time I will not go into the details of the modular approach, but they are attached as an Appendix to this statement.

"Notified bodies" will be created when the Member State "notifies" to the Commission those testing bodies that are competent to perform testing to support a particular directive. These "notified bodies" will then appear in an Appendix to the directive. At the present time, it is the Commission's intention not to allow Member States the opportunity to "notify" competent U.S. laboratories to support the export of U.S. manufactured product to the EC.

Competency would be judged on the EN 45000 series of standards.

It is unclear whether the Commission will allow EC-based laboratories operating in the U.S. to achieve "notified body" status. If they were to do so EC-owned laboratories could test for both markets and U.S. laboratories would be seriously disadvantaged. If this becomes EC policy, it will clearly violate the princple of national treatment, which would dictate that U.S. laboratories be afforded the same opportunity to become "notified bodies" as will be enjoyed by EC laboratories. The directive on Electromagnetic Compatibility testing (also known as EMC), a regulated area, illustrates how such an EC policy would disadvantage U.S. laboratories, but also shows how such a policy can be challenged.

The U.S. currently operates a certification system for EMC laboratories under Part 15 of its rules. Some devices are self-certified while others are certified by the FCC based on data supplied by a "listed" laboratory. Any laboratory in the world can become a "listed" laboratory based on FCC certification criteria. Currently there are four (4) EC-based laboratories on list: STL and ERA in the U.K.; Olivetti in Italy; and Radio Frequency Technology in Ireland. Of course, U.S. laboratories are also certified, performing testing for U.S. industry, but also for the EC. The FCC reviews the data received from these laboratories, and if acceptable, issues a grant of certification within eight weeks. There is federal preemption under this program.

It is clear that the U.S. system is open and transparent. The proposed EC system is not: the Commission does not plan to "notify" U.S. laboratories.

Now it is important to note that both the U.S. and EC programs are regulated by their respective federal governments. Because of U.S. Federal government regulation, the FCC and USTR are prepared to close the FCC program for foreign laboratory participation unless the EC is willing to negotiate on the issue of "notified body" status. But for this centralized, government certification program, armed with the tools necessary to pry-open the EC market in a government-to-government negotiation, many of ACIL's small and medium sized EMC laboratories would be put out of business.

Now you will hear that there are subtleties attached to the EC "notified bodies" scheme: i.e., "notified bodies" may subcontract to U.S. laboratories for testing regulated under EC directives. However, it is important to note that there is absolutely no competitive advantage for EC "notified bodies" to do so. The U.S. laboratory would be in direct competiton with the EC "notified body." In addition, all current bilateral agreements between U.S. and EC laboratories in regulated products areas will be subject to renegotiation at the Commission level after 1992, or at the effective date of the particular product directive. Finally, while a U.S. laboratory could set-up a U.S.-owned subsidiary in an EC Member State and seek "notified body" status, this is clearly an artificial incentive to invest in the EC and well beyond the means of many small and medium sized laboratories. In addition, it is probable that EC Member States will seek to limit the number of "notified bodies" within the Community.

The above discussion relates only to those areas where the Commission has decided to regulate. There are many unregulated product areas. To handle these, the Commission will enter into a Memorandum of Understanding with CEN/CENELEC creating a structure called the European Organization of Testing and Certification (EOTC). EOTC is a structure designed to organize the private sector in the areas of testing and certification in the European Community. EOTC is organized into a Council, sectoral committees along industry disciplines, specialized committees along functional disciplines and agreement groups.

A review of the currently anticipated sectoral committees shows striking similarity to U.S. Industry Sector Advisory Committees (ISACs). In addition, ACIL learned in a recent mission to the EC that the proposed agreement groups (composed mainly of test houses and laboratories) will be open to participation from non-EC based laboratories. The question here however is whether small and medium-sized laboratories, currently serving U.S. suppliers to the EC market, will be able to martial resources necessary to participate in such groups. It is imperative for incentives to be provided for such participation, because if these agreement groups are truly open, U.S. industry could ally itself with non-European laboratories to prevent European domination in such groups. Clearly, ACIL believes that the current unregulated U.S. system be re-evaluated in light of the development of EOTC.

The final part in the EC scheme, and the most difficult to understand, is treatment of products that are unregulated in the U.S., but regulated in the EC. The EC Construction Products Directive is a useful example.

A review of the Construction Products Directive shows that all construction products are covered. In the U.S. however, very few construction products are regulated at the Federal level. Most are regulated at the state, local and muncipal level in specific codes. This is especially true in the areas of safety. For U.S. laboratories wishing to continue to serve U.S. suppliers to the EC market, they must become "notified bodies." In a case such as this, the Commission would be willing to enter into a negotiation on a product-by-product basis, but such that a mutual recognition agreement would "establish a balanced situation with regard to the advantages derived by the parties in all matters relating to conformity assessment for the products concerned."

The first question that needs to be answered is: who will negotiate access? Because the product is regulated by EC, they are looking for a federal government-to-government dialogue. They will not recognize the various U.S. state, local or private sector entities for the purposes of binding national legal obligations. The second question is: with such a decentralized and unorganized U.S. system, how can the U.S. offer the E.C. the "balanced situation" it is seeking for the purposes of mutual recognition agreements. Again, ACIL is not proposing a solution at the present time, but is advocating an evaluation of the current U.S. system in light of these international developments.

I would like to conclude this second section of our statement with an area of laboratory services that has yet to be tackled by the EC or Eastern Europe in general - and that is the area of environmental testing.

In the United States, there are presently more than 75 individual State environmental laboratory accreditation programs, many of which are not recognized by other State accreditation agencies. A total of 44 states utilize EPA performance evaluation samples and many conduct their own audits of laboratory facilities. Unfortunately, most of these accreditation programs do not have identical requirements. In some cases, the requirements from different agencies may actually conflict with one another, thereby requiring the laboratory to perform a particular procedure several different ways in order to satisfy the requirements of each program. Many accreditation programs involve laboratory site visits, laboratory audits and analysis of proficiency samples for evaluation by the accrediting agency.

These redundant and conflicting requirements pose a significant burden on the laboratories and the users of laboratory services, while providing very little improvement in data quality. In order to be fiscally viable, any environmental laboratories have extended their markets to include multiple States. It is not unusual for a modest sized laboratory to incur costs of $75,000-$100,000 annually for these various accreditations. ACIL's current membership is more than half environmental laboratories.

Now why do I raise this area of testing and certification even though the Commission has yet to address it? First, a representative of the European Commission has stated that the principles of the Global Approach will apply to non-product certifying type laboratory services (such as environmental). This means that the "notified bodies" principle will apply because the directives envision Commission regulation in the areas of health, safety and the environment. Therefore in order for U.S. laboratories to gain access to the EC market for environmental services, a government-to-government negotiation would have to take place based on the "balanced situation" principle enunciated earlier. There is no way that the U.S. government can guarantee a balanced situation with 75 redundant and conflicting accreditation programs at all levels of government. These are non-tariff barriers to the Europeans.

Now a dose of reality. The EC attempts to protect the environment are behind that of the U.S. They don't have the statutory mandates, the testing and certification infrastructure, or the analytical equipment. One thing they do have, however, is pollution. The 1990's is touted as the "Decade of the Environment" in the EC. This is a clear case where the United States could show a leadership role in assisting the EC in developing test methodologies; advising them on statutory approaches that don't work; and assisting the U.S. environmental community in creating a rational testing and certification infrastructure in the U.S. that can relate to that developing in the EC. Such vision could avoid many of the difficulties that we are currently experiencing in the product certification area with the EC.

Consideration of these realities makes ACIL concerned about the competitiveness of the United States and its ability to respond creatively to developments worldwide in the testing, certification and accreditation fora. Will qualified small and medium-sized laboratories be able to participate in the global marketplace? Will the creation, operation and coordination of regional testing and certification bodies work to the detriment of the current U.S. system? Will the U.S. be able to effectively address non-tariff barriers because of limitations in current U.S. trade law and our current governmental and private sector administrative structure?

ACIL believes that there is a legitimate role for both the public and private sector in fashioning a coordinated and systematic U.S. response to worldwide developments in the testing industry. And in order to development such a response, a complete re-examination of the U.S. testing, certification, and accreditation industry needs to be undertaken, squared with development internationally, and performed by a Congressional chartered National Commission.

The system that ACIL would support would include, but would not be limited to, some of the following elements: principally private sector, subject to Congressional oversight, open and transparent, subject to administrative procedures required by law, non-preemptive of existing Federal programs unless requested by the affected agency, and contain sufficient checks and balances. Functions of such a system would include, but would not be limited to (1) the reciprocal acceptance of test data internationally; (2) the recognition of U.S. laboratory accreditation schemes; and (3) the negotiation of U.S. laboratory access internationally.

We started off today with an examination of the history of the federal role in testing and certification; and then examined its current state; and finally we have offered a very small solution that may offer competitive assistance to the U.S. testing industry in light of worldwide regional consolidation efforts. To use Mr. Drucker's words again,... (w)ithin self-imposed limitations...." we have attempted to set the agenda today,"...in contemplation of tomorrow."

Thank you for the opportunity to testify.

PENNIMAN & BROWNE, INC.

HERBERT E. WILGIS, JR.
PRESIDENT

EDUCATION: AB, Princeton University (High Honors), 1957

EXPERIENCE:

1986 - Present: President and CEO, Penniman & Browne, Inc.

Mr. Wilgis assumed the Presidency of Penniman & Browne, Inc. on October 1, 1986. He reorganized the company and, coincident with a growing need for environmental sampling and analysis, amplified its capabilities in this field through recruitment of personnel, acquisition of equipment, and adoption of procedures which conform to standards of the Environmental Protection Agency and corresponding offices on the State and local levels. He recruited additional personnel to expand the scope of the company's engineering, industrial hygiene and metallurgical departments.

1958 - 1986: Department of State, Washington, D.C.

Prior to his association with Penniman & Browne, Mr. Wilgis was a career Foreign Service Officer of the United States of America, attaining the rank of Minister Counselor. His assignments since 1977 were American Consul General, Barcelona, Spain (1983-1986); Minister Counselor and later Charge of the American Embassy, Warsaw, Poland (1981-1983); and Counselor of the American Embassy, Budapest, Hungary (1977-1980). Earlier assignments were to Germany, Hungary, Honduras, Spain and the Department of State in Washington, D.C. Mr. Wilgis is the recipient of the Department of State's Meritorious Honor and Superior Service Awards. His languages include Spanish, German, Hungarian and Polish in addition to his native English.

Mr. Wilgis is the company's representative to the American Council of Independent Laboratories (ACIL) and active in that organization's Government Affairs and Public Relations Committees. In 1989 he was named Chairman of ACIL's Laboratory Accrediation Subcommittee and Vice-Chairman of the Government Affairs Committee.

Mr. **Valentine**. Mr. Bhatia.

Mr. **Bhatia**. Good morning, Mr. Chairman. My name is Joe Bhatia. I come to you from Underwriters Laboratories, better known as UL.

Our primary function at UL is to develop safety standards, to investigate products, and to conduct factory production inspections. Last year alone, the famous UL mark in a circle appeared on more than seven billion products that entered the marketplace. We investigated products in over 13,000 different types of categories for 40,000 client companies.

For the past several years, UL has been operating an international compliance services program to assist American industry in their exporting activity. Last year, responding to international developments, we established a quality registration program which we felt was sorely needed.

When considering the broad range of purposes for which testing or certification can take place, it must be emphasized that programs related to safety, health and well-being of the public are most critical. These are the areas that we are active in. In these activities, the proper role of the third party certifier is vital because these organizations don't just determine compliance with a product standard; they also carry out numerous other critical activities. One of these is to establish compatibility with national, state and local codes and standards. As you know, these codes can cover installation, electrical construction, plumbing, fire and other end-use requirements which are not normally found in standards.

The key point to remember is this: product safety certification is not a simple process, and certainly it's not just conducting testing in a laboratory, although testing is an element of it. The consequences of failing to properly conduct product safety certifications are awesome. People can be injured or killed, certification agencies can be sued, regulators and consumers can lose confidence in the certification process, and the loss of stability in the marketplace can become a competitive headache for manufacturers. Safety certification, ladies and gentlemen, is a serious business.

Although the creation of EC 1992 is not the only international development that should be considered, it is obviously the key motivator behind the debate on how to improve the U.S. effectiveness in the international marketplace.

As we heard this morning, presently several unanswered questions remain as to how the EC system would work in the areas of testing and certification, especially as related to non-EC, non-EFTA countries. EOTC is obviously the coordinating body for all nonregulated products—and there are plenty of those that we need to worry about. But the structure and leadership of EOTC has not even been established yet.

Although the final answer to whether the changes in Europe will be of benefit or of detriment to U.S. industry is still not obvious, one thing is clear: a tremendous amount of time and effort is being expended to institutionalize the concepts of quality and quality systems, both in regulated and nonregulated areas. It is essential for the U.S. exporters to understand the increasing importance of quality and its codification into international and regional national standards within EC and beyond. Compliance with ISO 9000 series documents is fast becoming an element of the purchaser/supplier contract agreements. Therefore, in many cases, testing and certification activities will have to be supported by quality registration of manufacturing facilities.

Now, what is the impact of international developments on the U.S.? That's why we're here. In response to foreign developments, presently there is a great deal of debate in the U.S. whether accreditation of laboratories and accreditation of certifiers is necessary as a means to obtain easier access to foreign markets. The discussions also cover whether the accreditation should take place in the government or private sector. The principal concern that many people have with accreditation programs is that they can be perceived as assuring that accredited laboratories, or the accredited certifiers, are capable of producing accurate test results, which are needed, or conducting effective certifications, which are needed, when, in fact, most evaluation criteria used in most programs do not and cannot provide such assurance. Yet, where safety is involved, such assurance is critical.

This assurance cannot be obtained in a simplistic approach involving an accreditation scheme, even one managed by a government agency. It is also important to note that conduct of a comprehensive accreditation program is time-consuming and extremely expensive. Therefore, its overall need, its value-added benefit to the manufacturers and the U.S. industry and its economic impact on the accredited organizations and the industry would have to be determined before implementation. And perhaps most significantly, it must be determined whether accreditation by a U.S.-based entity, public or private, will actually assist U.S. industry in gaining better access to international markets. In other words, will non-U.S. entities accept such U.S. accreditations?

Now let's look at the role of the Federal Government. Obviously, in many areas where products are regulated, both by the EC and the U.S., the EC will logically want to interact with corresponding government authority in the U.S. Certain interactions and negotiations will and should involve U.S. Government participation. In the nonregulated areas, both EC and EOTC have indicated a willingness to work with organizations in the private sector. The existing and new agreements, memoranda of understanding, and subcontracting agreements will be coordinated through EOTC. The U.S. testing labs can participate.

In the regulated areas, the manufacturer's declaration of conformity allows the use of U.S. laboratories as much as the European laboratories. Also, there is a good likelihood that methodically developed agreements between the U.S. labs and their European counterparts can be consummated just as some have been in the past. This approach will allow U.S.-developed work and data packages to be accepted with confidence in the EC conformity assessment process, even without the official notified body status.

From the U.S. viewpoint, a very critical question to consider is this: in return for easier access, what demands might be placed on U.S. certifiers, U.S. testing labs, regulatory authorities, and others? The EC, its member states, and the European notified bodies will most certainly demand a quid pro quo. This would mean that products certified by all notified bodies in Europe, 12, 20, hundreds, or perhaps even thousands of such bodies, may have to be accepted in the U.S. by authorities, by testing labs, and by certifiers. Who will determine the competence of these organizations, and how? Will these products be evaluated to U.S. standards and installation codes? We don't know. Is American industry going to put up with commercial differentials—in other words, compete at the same price for products produced to a different set of specifications, validated by foreign entities? What will be the burden on our jurisdictional parties at Federal, state and local levels who, by our own laws, are charged with the responsibility of protecting public life, property and the environment? What can consumers expect? Will the safety levels provided and expected in our Nation be compromised? I hope not.

Clearly, answers to these questions must be considered before embarking on a U.S. strategy to deal with EC. So what should we do? What should the U.S. objectives be? The primary U.S. strategy ought to be to achieve fair trade via equal and competitive access to foreign markets by U.S. manufacturers. In my complete statement I have outlined seven key elements and initiatives that could form the basis of our approach.

As a final comment, Mr. Chairman, I would like to note that while it's nice and important to listen to laboratories and certifiers, the true assessment of U.S. industry's international competitiveness needs can be best made by hearing from the industry itself. Therefore, input from the appropriate U.S. industry sector should be sought and strongly considered before embarking on a U.S. strategy relative to testing, certification and quality assessment procedures.

I thank you.

[The prepared statement of S. Joseph Bhatia follows:]

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STATEMENT OF

UNDERWRITERS LABORATORIES INC.

ON

"THE FEDERAL ROLE IN INTERNATIONAL TESTING, CERTIFICATION AND QUALITY ASSURANCE"

BEFORE THE

SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY

HOUSE SCIENCE, SPACE AND TECHNOLOGY COMMITTEE

JUNE 26, 1990

An independent
not-for-profit organization
testing for public safety

TESTIMONY TO

SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY

HOUSE SCIENCE, SPACE AND TECHNOLOGY COMMITTEE

JUNE 26, 1990

GOOD MORNING. I AM JOE BHATIA, VICE PRESIDENT, GOVERNMENTAL AFFAIRS, UNDERWRITERS LABORATORIES INC. (UL). UL'S INVOLVEMENT AND INTEREST IN THE AREAS OF STANDARDS, TESTING, QUALITY AND CERTIFICATION, BOTH IN THE U.S. AND INTERNATIONALLY, IS VERY EXTENSIVE. THEREFORE, I AM MOST PLEASED TO PRESENT OUR VIEWS ON THE U.S. PARTICIPATION IN INTERNATIONAL TESTING AND CERTIFICATION RELATED ACTIVITIES.

UL BACKGROUND

BY THE WAY OF BACKGROUND, UL IS THE LARGEST PRIVATE PRODUCT SAFETY TESTING AND CERTIFICATION ORGANIZATION IN THE WORLD. LAST YEAR ALONE, MORE THAN 6,000,000,000 PRODUCTS WERE MANUFACTURED WITH THE UL LISTING MARK. WE INVESTIGATED PRODUCTS IN MORE THAN 13,000 CATEGORIES FOR 40,000 CLIENT COMPANIES. UL HAS DEVELOPED, IN COOPERATION WITH INDUSTRY AND THE U.S. SAFETY SYSTEM, OVER 550 PRODUCT SAFETY STANDARDS. WE ALSO PARRTICIPATE IN MORE THAN 500 STANDARDS COMMITTEES OF OTHER ORGANIZATIONS, INCLUDING MORE THAN 135 INTERNATIONAL STANDARDS COMMITTEES.

FOR THE PAST SEVERAL YEARS, UL HAS BEEN OPERATING INTERNATIONAL COMPLIANCE SERVICES PROGRAMS TO ASSIST AMERICAN MANUFACTURERS AND EXPORTERS WITH INTERNATIONAL AND FOREIGN NATIONAL SAFETY CERTIFICATION REQUIREMENTS, STANDARDS, AND PRACTICES. RESPONDING TO THE INTERNATIONAL DEVELOPMENTS AND THE NEEDS OF U.S. INDUSTRY FOR QUALITY ASSESSMENT, UL ESTABLISHED A QUALITY REGISTRATION PROGRAM IN AUGUST, 1989.

UL'S PRIMARY FUNCTION IS THE SAFETY CERTIFICATION OF PRODUCTS AND SYSTEMS THROUGH INVESTIGATIONS AND FACTORY INSPECTIONS TO DETERMINE CONFORMITY WITH THE SAFETY REQUIREMENTS.

UL CONDUCTS NEARLY ONE-HALF MILLION FACTORY FOLLOW-UP INSPECTIONS PER YEAR TO DETERMINE CONTINUED CONFORMITY OF AND SYSTEMS. (OVER SIX BILLION MARKS WERE ISSUED LAST YEAR.)

UL ALSO CONDUCTS A COMPREHENSIVE STANDARDS DEVELOPMENT ACTIVITY (APPROXIMATELY 561 PRODUCT SAFETY STANDARDS NOW ISSUED).

TESTING AND CERTIFICATION

FIRST OF ALL, IT IS IMPORTANT TO NOTE THAT MOST OF THE PRODUCT TESTING CARRIED OUT IN THE U.S. AND ELSEWHERE DOES NOT RESULT IN CERTIFICATION.IT IS CONDUCTED FOR DEVELOPMENT, RESEARCH, COMPATIBILITY, QUALITY, PERFORMANCE, OR OTHER PURPOSES. THEREFORE, THE NUMBER OF LABORATORIES WHO CONDUCT THESE KINDS OF TESTS FAR EXCEEDS THOSE THAT CARRY OUT TESTING FOR CERTIFICATION PURPOSES.

TODAY, IN OUR NATION, PRODUCT CERTIFICATION SCHEMES SPAN THE FULL RANGE FROM SIMPLE TO COMPLEX. THERE ARE MANY PRIVATE ORGANIZATIONS, AS WELL AS FEDERAL, STATE, AND LOCAL GOVERNMENT AGENCIES, IN THE U.S. THAT CERTIFY PRODUCTS.

IN RECENT YEARS, THE IMPACT OF CERTIFICATION PROGRAMS ON TRADE IN BOTH DOMESTIC AND INTERNATIONAL MARKETS HAS BECOME INCREASINGLY PROMINENT. IT IS RECOGNIZED THAT ACTIVITIES SUCH AS CERTIFICATION PROGRAMS CAN EITHER EXPEDITE OR SERIOUSLY HINDER THE FREE FLOW OF GOODS IN INTERNATIONAL COMMERCE.

IN GENERIC TERMS, THE CERTIFICATION PROCESS CAN TAKE TWO FORMS: (1) SELF-CERTIFICATION IN ITS VARIOUS FORMS AND (2) A MYRIAD OF THIRD PARTY CERTIFICATIONS.

WHEN CONSIDERING THE BROAD RANGE OF PURPOSES FOR WHICH CERTIFICATION PROGRAMS ARE CONDUCTED, IT SEEMS CLEAR THAT PROGRAMS RELATED TO SAFETY, HEALTH, AND WELL-BEING ON THE PUBLIC ARE MOST IMPORTANT. IN THESE ACTIVITIES, THE ROLE OF THE THIRD PARTY CERTIFIER IS VITAL BECAUSE, IN GENERAL, MANY OF THE ORGANIZATIONS INVOLVED DO NOT JUST DETERMINE COMPLIANCE WITH A PREVAILING PRODUCT STANDARD; THEY ALSO SHOULD ESTABLISH COMPATIBILITY WITH NATIONAL, STATE, AND LOCAL CODES AND STANDARDS. THESE CODES COVER INSTALLATION, ELECTRICAL, CONSTRUCTION, PLUMBING, FIRE AND OTHER END-USE REQUIREMENTS.

WITHOUT SUCH COMPATIBILITY INFORMATION, REGULATORY AUTHORITIES CANNOT CARRY OUT THEIR LEGAL RESPONSIBILITY OF DETERMINING THAT ALL ELEMENTS OF AN EFFECTIVE PROGRAM ARE EMPLOYED IN ESTABLISHING PRODUCT SAFETY CERTIFICATIONS, NOT JUST A FEW. ADDITIONALLY, MANUFACTURERS NEED CERTIFICATIONS THAT ARE SUFFICIENTLY COMPREHENSIVE TO MEET THE MARKETPLACE REQUIREMENTS IN ALL JURISDICTIONS, SO THAT THEY CAN INTRODUCE THEIR PRODUCTS INTO COMMERCE. FINALLY, THE PUBLIC HAS A RIGHT TO BE ABLE TO CORRECTLY UNDERSTAND THE CERTIFICATIONS AS REPRESENTED BY A PRODUCT MARKING - I.E., THESE MARKINGS MUST RELATE TO THE ACTUAL PRODUCT BEING PURCHASED AND NOT A PROTOTYPE LABORATORY SAMPLE, OR INDIRECTLY TO SOME ACCREDITATION SCHEME. THIS CAN ONLY BE ASSURED BY COMPREHENSIVE AND RELIABLE THIRD PARTY SAFETY CERTIFICATIONS.

NEEDS SIMILAR TO THOSE DESCRIBED HEREIN ALSO EXIST IN THE INTERNATIONAL ARENA IN THE AREAS OF HEALTH, SAFETY, AND PUBLIC WELFARE. ALTHOUGH THESE NEEDS MAY BE ADDRESSED DIFFERENTLY IN DIFFERENT NATIONS, NEVERTHELESS THEY MUST BE CONSIDERED.

BEFORE DISCUSSING ACCREDITATION AS IT RELATES TO PRODUCT SAFETY CERTIFIERS, IT IS IMPORTANT THAT TWO KEY QUESTIONS BE ANSWERED: FIRST, WHAT ELEMENTS ARE NECESSARY TO MAINTAIN SAFETY? SECOND, WHAT CONSTITUTES A PROPER SAFETY CERTIFICATION PROGRAM?

THE ANSWERS CAN BE BEST PROVIDED PERHAPS BY MAKING THE POINT THAT THE PRODUCT SAFETY CERTIFICATION PROCESS IS NOT SIMPLE. THE CONSEQUENCES OF FAILING TO PROPERLY CONDUCT PRODUCT SAFETY CERTIFICATIONS ARE AWESOME: PEOPLE CAN BE INJURED OR KILLED, CERTIFICATION AGENCIES CAN BE SUED, MANDATORY GOVERNMENT STANDARDS CAN REPLACE THE MORE

FLEXIBLE VOLUNTARY STANDARDS, REGULATORS AND CONSUMERS CAN LOSE CONFIDENCE IN THE CERTIFICATION PROCESS, THE LOSS OF STABILITY IN THE MARKETPLACE CAN BECOME A COMPETITIVE HEADACHE FOR MANUFACTURERS, AND PROGRESS IN THE USE OF CERTIFICATIONS TO REDUCE BARRIERS TO TRADE CAN BE INHIBITED. SAFETY CERTIFICATION IS A SERIOUS BUSINESS.

ACCREDITATION

UL'S VIEWS ON LABORATORY ACCREDITATION AS WELL AS CERTIFIER ACCREDITATION SCHEMES HAVE BEEN FORMULATED BASED ON 96 YEARS OF EXPERIENCE WITH THE TESTING, FACTORY INSPECTION, AND CONTROL OF THE USE OF OUR CERTIFICATION MARK.

IN THE U.S., A DEGREE OF CONFUSION EXISTS BETWEEN THE TERM "LABORATORY ACCREDITATION" AND "CERTIFICATION". THESE TERMS ARE OFTEN USED INTERCHANGEABLY WHEN, IN FACT, THE TWO PROCESSES ARE RADICALLY DIFFERENT. THE STATED GOAL OF MOST

LABORATORY ACCREDITATION PROGRAMS IS TO VERIFY THAT A LABORATORY PROVIDING SPECIFIC TESTING SERVICES IS TECHNICALLY COMPETENT TO CARRY OUT THE TEST WORK IN A SPECIFIC SERIES OF TEST PROTOCOLS OR IN COMPLIANCE WITH A PARTICULAR TESTING DOCUMENT. THE NATURE OF ACCREDITATION CRITERIA AND THEIR IMPLEMENTATION VARY GREATLY AMONG PROGRAMS.

CERTIFICATION, ON THE OTHER HAND, IS A PROCESS THAT IS CONFORMANCE BASED,IN WHICH PRODUCT TESTING AND DEMONSTRATING COMPLIANCE WITH A PARTICULAR STANDARD ARE JUST TWO OF THE MANY ESSENTIAL ELEMENTS THAT MUST BE CONSIDERED.

A PRINCIPLE CONCERN WITH LABORATORY ACCREDITATON PROGRAMS IS THAT THEY CAN BE PERCEIVED AS ASSURING THAT THE ACCREDITED LABORATORIES ARE CAPABLE OF PRODUCING UNIFORM AND ACCURATE RESULTS WHEN, IN FACT, THE EVALUATION CRITERIA USED IN MOST PROGRAMS DO NOT PROVIDE SUCH ASSURANCE. YET, WHERE SAFETY IS INVOLVED, SUCH ASSURANCE IS CRITICAL.

ACCREDITATION OF CERTIFICATION PROGRAMS IS MADE EVEN MORE DIFFICULT BY THE FACT THAT COMPLEXITIES ARE INTRODUCED THROUGH ADDITIONAL CRITICAL ELEMENTS THAT MUST BE EVALUATED.

WHAT IS MOST SIGNFICANT IS THAT THE CONDUCT OF A COMPREHENSIVE ACCREDITATION PROGRAM IS TIMING CONSUMING AND EXPENSIVE. ESPECIALLY WHERE SAFETY IS PARAMOUNT, THE ACCREDITATION FILING PROCESS MUST BE COMPREHENSIVE, PERIODIC PROFICIENCY TESTING IS NECESSARY, INITIAL AND FOLLOW-UP ON-SITE INSPECTIONS ARE ESSENTIAL, AND, WITHOUT DEACCREDITATION PROCEDURES AND CONTROLS, THERE REALLY IS NO PROGRAM, I.E., IT IS A PROGRAM IN NAME ONLY.

IT IS IMPORTANT TO NOTE THAT THIS COMPREHENSIVE APPROACH REQUIRES EXTENSIVE TIME AND MONETARY COMMITMENT BOTH ON THE PART OF THE ACCREDITING ORGANIZATION AS WELL AS THE ORGANIZATION BEING ACCREDITED. UNFORTUNATELY, TO DATE, WE HAVE NOT SEEN ANY SIGNIFICANT PROGRESS, EITHER NATIONALLY OR INTERNATIONALLY, IN ACCREDITATION PROCEDURES RESULTING IN THE INCLUSION AND APPLICATION OF ALL OF THE CRITICAL ELEMENTS THAT MEANINGFULLY DEMONSTRATE THE COMPETENCE OF AN ACCREDITED ORGANIZATION.

IF SUCH A COMPREHENSIVE NATIONAL OR INTERNATIONAL ACCREDITATION PROGRAM WERE DEVELOPED, THE OVERALL NEED, VALUE-ADDED BENEFIT TO THE INVOLVED INDUSTRY SECTOR, AND ECONOMIC IMPACT OF SUCH A PROGRAM ON THE ACCREDITED ORGANIZATION AND THE INDUSTRY WOULD HAVE TO BE IDENTIFIED AND ASSESSED BEFORE IMPLEMENTATION.

ADDITIONALLY, WHERE PRODUCT SAFETY CERTIFICATION IS INVOLVED, THE FOLLOWING CONCERNS REGARDING LABORATORY ACCREDITATION MUST BE STATED:

(1) THE PERCEPTION BY OUTSIDERS THAT LABORATORY ACCREDITATION MEANS FAR MORE THAN ANY ACCREDITATION PROGRAM IS CAPABLE OF DELVERING. MOST PROGRAMS TEND TO CONCENTRATE ON DETERMINING THE PRESENCE OF FACILITIES, TEST EQUIPMENT, STAFF, AND THE EXISTENCE OF SOME LIMITED PROCEDURES. WHILE A FEW PROGRAMS EVEN INVOLVE CURSORY ON-SITE VISITS, THERE IS FAR MORE REQUIRED IN DETERMINING ONGOING COMPETENCE OF A LABORATORY. A ONE-TIME EXAMINATION OF A LABORATORY DOES NOT MEAN VERY MUCH.

(2) A GREATER CONCERN IS THE CONFUSION THAT EXISTS, OR IS OTHERWISE PERPETUATED, BETWEEN LABORATORY ACCREDITATION AND PRODUCT SAFETY CERTIFICATION. MANY KEY FEATURES OF PRODUCT SAFETY CERTIFICATION - SUCH AS:

- COMPLIANCE WITH ALL THE APPLICABLE TESTING AND CONSTRUCTION REQUIREMENTS OF PRODUCT STANDARDS;
- DETERMINATION OF COMPLIANCE WITH ALL APPLICABLE CODES;
- INVESTIGATION OF PRODUCT COMPONENTS, MATERIALS, ASSEMBLY, AND DESIGN FEATURES;
- ONGOING VERIFICATION OF PRODUCTION PROCESSES;
- TESTING OF OPEN MARKET AND PRODUCTION SAMPLES;
- CORRECTIVE ACTION PROGRAMS; AND
- USE AND CONTROL OF THE CERTIFICATION MARK -

ARE NOT THE AREAS OF CONCERN IN LABORATORY ACCREDITATION PROCESSES, BUT RATHER ARE CRITICAL TO THE SAFETY PERFORMANCE OF PRODUCTS.

(3) ACCREDITATION PER SE DOES NOT RELATE TO THE PRODUCT OR ITS MANUFACTURE. NOTHING IN THE PROCESS ASSURES PURCHASERS THAT A PRODUCT CONFORMS TO A SPECIFIC STANDARD OR MEETS OTHER CRITERIA. AND, CERTAINLY, REGARDLESS OF ANY CLAIMS, THE LABORATORY ACCREDITATION PROCESS BY ITSELF DOES NOT ESTABLISH COMPLIANCE WITH PRODUCT PERFORMANCE OR SAFETY REQUIREMENTS.

IN RESPONSE TO INTERNATIONAL DEVELOPMENTS, CURRENTLY THERE IS A GREAT DEAL OF DEBATE IN THE U.S. REGARDING ACCREDITATION OF LABORATORIES AND CERTIFIERS AS A MEANS TO OBTAIN EASIER ACCESS TO INTERNATIONAL MARKETS. THE DELIBERATIONS ALSO INCLUDE DISCUSSIONS ON HOW THINGS WILL DEVELOP IN THE U.S. AND WHETHER THE EUROPEANS, ESPECIALLY EC ENTITIES, WILL FORCE THE ISSUE OF A NATIONAL ACCREDITOR

ON U.S., AND WHETHER THIS ACCREDITOR NEEDS TO BE A GOVERNMENTAL OR A PRIVATE ORGANIZATION.

INTERNATIONALLY, U.S. MANUFACTURERS HAVE A NEED TO GET THEIR PRODUCT EVALUATIONS CONDUCTED IN A MANNER THAT ASSISTS THEM IN GAINING ACCESS TO FOREIGN MARKETS. WITHIN U.S., FEDERAL, STATE, AND LOCAL AGENCIES, REGULATORY OFFICIALS, INSPECTION AUTHORITIES AND INSURANCE INTERESTS OFTEN LOOK FOR THIRD-PARTY CERTIFICATIONS OR VALIDATION. MAJOR RETAILERS AND DISTRIBUTORS SEEK SOME GUARANTEED THAT EVERY EFFORT WAS MADE FOR THE PRODUCTS THEY SELL TO BE BOTH SAFE AND RELIABLE. THESE GROUPS WHO RELY ON TESTING AND CERTIFICATION NEED A SYSTEM THAT TRULY WORKS. AN ACCREDITATION PROGRAM - EITHER IN PUBLIC OR PRIVATE SECTOR, WHICH DOES NOT CONTAIN ALL THE ESSENTIAL ELEMENTS OF A SAFETY CERTIFICATION SCHEME OR A LABORATORY ACCREDITATION CRITERIA WILL, AT BEST, MISLEAD AND, AT WORST, RESULT IN THE ACCEPTANCE OF NON-COMPLYING AND/OR UNSAFE PRODUCTS IN THE MARKETPLACE.

INTERNATIONAL DEVELOPMENTS

EC DEVELOPMENTS:

ALTHOUGH THE CREATION OF THE EUROPEAN INTERNAL MARKET, EC 1992, IS NOT THE ONLY INTERNATIONAL DEVELOPMENT THAT SHOULD BE CONSIDERED, IT IS THE KEY MOTIVATOR BEHIND THE DEBATE ON HOW TO IMPROVE THE U.S. SYSTEM TO ASSIST OUR INDUSTRIES IN INTERNATIONAL COMMERCE.

PRESENTLY, SEVERAL UNANSWERED QUESTIONS REMAIN AS TO HOW THE EC SYSTEM WILL WORK IN THE AREAS OF TESTING AND CERTIFICATION, ESPECIALLY AS RELATED TO NON-EC, NON-EFTA COUNTRIES.

ONE FACT IS CLEAR. THE ACCEPTANCE OF PRODUCTS INTO THE EC SYSTEM WILL BE LARGELY DEPENDENT ON WHETHER THESE PRODUCTS ARE REGULATED OR NON-REGULATED. THE EC DIRECTIVES WILL SPELL OUT HOW MANUFACTURERS CAN AFFIRM CONFORMITY WITH THE ESSENTIAL REQUIREMENTS AND EN STANDARDS. THE REQUIREMENTS WILL VARY WITH THE DEGREE OF RISK OR DANGER PRESENTED

BY THE PRODUCT. IN SOME INSTANCES, MANUFACTURERS CAN SIMPLY DECLARE COMFORMITY. IN OTHERS, A THIRD-PARTY CERTIFICATION WILL BE REQUIRED. IN MANY CASES, MANUFACTURERS WISHING TO MARKET PRODUCTS IN EUROPE WILL HAVE TO MEET QUALITY ASSURANCE PROGRAMS DESCRIBED IN THE EN 29,000 SERIES STANDARDS. QUALITY SYSTEM IN A PLANT MUST BE REGISTERED BY A NOTIFIED BODY OR OTHER RECOGNIZED ORGANIZATION. INTERNATIONAL DEVELOPMENTS IN THE QUALITY AREA ARE ADDRESSED IN A SEPARATE SECTION OF THIS STATEMENT.

THE EC HAS ADOPTED A SINGLE COMMUNITY MARK, A CE MARK, WHICH CAN BE PLACED ON PRODUCTS OR CONTAINERS TO INDICATE CONFORMITY WITH THE ESSENTIAL REQUIREMENTS. FOR MANY PRODUCTS, WHERE A THIRD-PARTY INVOLVEMENT IS MANDATED BY A DIRECTIVE OR OPTIONALLY SELECTED VIA THE USE OF A PARTICULAR MODULE, THE MARK OF THE CERTIFICATION ORGANIZATION WILL BE PLACED ADJACENT TO THE CE MARK. THE CE MARK SERVES AS A

PASSPORT TO ENTER THE EUROPEAN MARKET. IT WILL, MOST LIKELY, NOT ASSURE PRODUCT ACCEPTANCE IN ALL CITIES AND JURISDICTIONS OF EUROPE, WHERE LOCAL SAFETY OR END-USE REQUIREMENTS AND NATIONAL TREATMENT CONTINUE TO EXIST FOR AN UNSPECIFIED PERIOD OF TIME.

UNDER THE GATT STANDARDS CODE, EQUAL ACCESS TO CONFORMITY ASSESSMENT PROCEDURES WILL BE PROVIDED TO FOREIGN MANUFACTURERS. IN THE NEW EC SCHEME, A PRODUCT ACCEPTED AND LAWFULLY SOLD IN ONE MEMBER COUNTRY MUST BE ACCEPTED BY OTHER MEMBER COUNTRIES.

QUALITY:

ALTHOUGH THE FINAL ANSWER TO WHETHER THE ELIMINATION OF INTERNAL TRADE BARRIERS IN EUROPE WILL BE OF BENEFIT OR

DETRIMENT TO U.S. MANUFACTURERS IS STILL TO BE DETERMINED, ONE THING IS CLEAR: A TREMENDOUS AMOUNT OF TIME AND EFFORT ARE BEING EXPANDED TO INSTITUTIONALIZE THE CONCEPTS OF QUALITY AND QUALITY SYSTEMS - BOTH IN REGULATED AND UNREGULATED AREAS. QUALITY APPEARS TO BE A COMMON THREAD TO MANY OF THE MAJOR DEVELOPMENTS IN THE WORLD OF STANDARDS, TESTING AND PRODUCT CERTIFICATION. IN THE REGULATED SECTOR, THREE OF THE EIGHT MODULES OF THE EC'S GLOBAL APPROACH DOCUMENT ON CONFORMITY ASSESSMENT ADDRESS QUALITY. SOME PRODUCT DIRECTIVES, ALTHOUGH NOT A LARGE NUMBER, SPECIFICALLY REQUIRE QUALITY ASSESSMENT AS PART OF THE ESSENTIAL REQUIREMENTS - E.G. MEDICAL DEVICES, INTRINSICALLY SAFE EQUIPMENT. ADDITIONALLY, MANY OF THE STANDARDS BEING DEVELOPED BY CEN AND CENELEC THAT WILL BE USED AS A BASIS TO DEMONSTRATE CONFORMITY WITH THE DIRECTIVES, CONTAIN QUALITY ASSESSMENT CRITERIA.

AN ESSENTIAL ELEMENT FOR THE U.S. MANUFACTURERS AND INDUSTRY WHO WISH TO EXPORT GOODS AND SERVICES TO EUROPE, IS TO UNDERSTAND THE INCREASING IMPORTANCE OF QUALITY AND ITS CODIFICATION INTO INTERNATIONAL AND REGIONAL STANDARDS PLANS. IN MANY CASES, CONFORMANCE TO ISO 9000 SERIES STANDARDS, WHICH ARE ESSENTIALLY REPRODUCED AS EN 29,000 SERIES DOCUMENTS IN THE EC SCHEME, IS CO-REQUISITE TO PRODUCT COMPLIANCE WITH THE REQUIREMENTS OF DEFINED TECHNICAL STANDARDS.

MOST OF THE EUROPEAN COUNTRIES ARE SCRAMBLING TO ESTABLISH A QUALITY ASSESSMENT AND CERTIFICATION PYRAMID WHICH INCLUDES NATIONAL ACCREDITATION ORGANIZATIONS, ASSESSMENT ORGANIZATIONS AND CERTIFIERS. THE LAST TWO MAY OR MAY NOT BE THE SAME ORGANIZATIONS. IN LARGE PART, THE SCHEMES ARE BEING MODELED AFTER THE BRITISH ONE WHICH HAS BEEN IN EXISTENCE FOR A NUMBER OF YEARS. OBVIOUSLY, DIFFERENT COUNTRIES ARE AT DIFFERENT STAGES OF DEVELOPMENT.

A REGIONAL EUROPEAN ORGANIZATION CALLED EQS, A HORIZONTAL COMMITTEE ON QUALITY UNDER THE EOTC STRUCTURE, HAS BEEN ESTABLISHED. WE HAVE BEEN INFORMED THAT

NO "STRUCTURAL IMPEDIMENTS" EXIST TO A U.S. LIAISON WITH THE EQS. HOWEVER, THE U.S. ORGANIZATION FULFILLING THIS ROLE MUST BE ACKNOWLEDGED BY THE U.S. QUALITY COMMUNITY AS THE UMBRELLA GROUP FOR ALL QUALITY WORK WITHIN OUR NATION.

ALTHOUGH QUALITY IS BEING HIGHLIGHTED IN EUROPE, IT IS BY NO MEANS LIMITED TO THAT REGION. CONCERN FOR QUALITY IS SWEEPING AROUND THE WORLD AND COMPLIANCE WITH QUALITY MEASURES ARE INCREASINGLY BEING INVOKED BY THIRD-WORLD COUNTRIES TO REDUCE THE DUMPING OF INFERIOR AND UNSAFE PRODUCTS, AND ARE FINDING THEIR WAY MORE AND MORE INTO CONTRACTS BETWEEN BUYERS AND SELLERS EVERYWHERE. IT APPEARS LIKELY THAT THE EN 29,000 SERIES/ISO 9000 SERIES DOCUMENTS WILL BE USED EXTENSIVELY BETWEEN PURCHASER AND SUPPLIER AS A MEANS OF DETERMINING THAT THE SUPPLIER IS ABLE TO PRODUCE GOODS TO THE PURCHASER'S EXPECTATIONS.

ALL THESE EFFORTS ARE AIMED AT INCREASING THE LEVEL OF CONFIDENCE BETWEEN PURCHASERS AND SUPPLIER FROM AROUND THE EC COMMUNITY AND THE WORLD. AS CONFIDENCE GROWS, THE FLOW OF GOODS SHOULD IMPROVE THROUGHOUT INTERNATIONAL MARKETS.

BUT SATISFACTION OF STANDARDS REQUIREMENTS IS ONLY ONE IMPETUS TO ESTABLISH A QUALITY ASSURANCE PROGRAM. ALTHOUGH QUALITY MAY NOT BE MANDATED FOR MANY PRODUCTS AS A MINIMUM LEGAL REQUIREMENT IN EC AND BEYOND, QUALITY MARKS - PERHAPS ON A NATIONAL SCALE INITIALLY - ARE LIKELY TO BECOME MARKETING COMPETITION TOOLS. MANY EUROPEAN ORGANIZATIONS ARE VYING TO BE THE ONE WITH THE MOST REPUTABLE MARK.

LOOKING BEYOND EUROPE, MANY OTHER INDUSTRIALIZED NATIONS ARE HOPPING ABOARD THE QUALITY BANDWAGON. JAPANESE

ORGANIZATIONS HAVE SIGNED MEMORANDA OF UNDERSTANDING WITH THE BRITISH STANDARDS INSTITUTE, BSI, AND UNDERWRITERS LABORATORIES (UL) IN U.S. OUR MAJOR TRADING PARTNER TO THE NORTH, CANADA RECOGNIZES THE SIGNFICANCE OF QUALITY ACTIVITY INTERNATIONALLY, AS A MUCH LARGER PERCENTAGE OF THEIR ECONOMIC ACTIVITY IS FOREIGN BASED.

IN THE U.S., IN RESPONSE TO INTERNATIONAL DEVELOPMENTS, ORGANIZATIONS LIKE AMERICAN GAS ASSOCIATION (AGA), UL AND PERHAPS OTHERS HAVE STARTED ASSESSING MANUFACTURERS' QUALITY SYSTEMS AGAINST THE ISO 9000 SERIES STANDARDS. NATURALLY, ONE OF THE DRIVING FORCES IN OBTAINING QUALITY SYSTEM REGISTRATION IS THE BENEFIT THAT SUCH A REGISTRATION WOULD HAVE FOR MANUFACTURERS IN EXPORTING BOTH THE REGULATED AND NON-REGULATED PRODUCTS TO EUROPE AND OTHER NATIONS.

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IN ORDER TO MAXIMIZE THE POTENTIAL BENEFITS OF OUR QUALITY REGISTRATION TO U.S.INDUSTRY, UL HAS PURSUED AND AND COMPLETED MEMORANDA OF UNDERSTANDING (MOUS), WITH OTHER QUALITY ASSESSORS AROUND THE WORLD. NAMELY:

BSI - (BRITISH STANDARDS INSTITUTION) A LEADING BRITISH QUALITY ASSESSOR AND PROBABLE NOTIFIED BODY FOR QUALITY ASSESSMENTS IN EC.

JMI - (JAPAN MACHINERY AND METALS INSPECTION INSTITUTE) JAPANESE QUALITY ASSESSOR

SII STANDARDS INSTITUTION OF ISRAEL

SA STANDARDS AUSTRALIA

ADDITIONAL MOUS ARE BEING PURSUED AT THIS TIME. A GLOBAL NETWORK OF AGREEMENT IS EVOLVING. IN THESE MOUS THE DATA EXCHANGE APPROACH TO COOPERATION BETWEEN ASSESSING BODIES IS FOLLOWED. AS CONFIDENCE GROWS, HOPEFULLY THE RECEIVING PARTY WILL FEEL LESS AND LESS NEED

TO CONDUCT ADDITIONAL WORK AND EFFECTIVE REGISTRATIONS WHICH WILL BE APPLICABLE THROUGHOUT THE WORLD. CAN BE OBTAINED BY MANUFACTURERS AT DECREASING COST. THESE MOUS WITH OTHER ORGANZIATIONS WHO ARE EXPECTED TO PLAY A LEADING ROLE IN IN THEIR NATION'S QUALITY ASSESSMENT AND REGISTRATION WILL ASSIST THE U.S. INDUSTRY IN OBTAINING MARKET ACCESS TO THOSE NATIONS WITHOUT UNDERGOING WITHOUT UNDERGOING REPETITIVE ASSESSMENTS.

EFFECTS OF INTERNATIONAL DEVELOPMENTS IN THE U.S.

OBVIOUSLY, IN MANY AREAS WHERE PRODUCTS ARE REGULATED BY THE EC AND THE U.S., EC WILL LOGICALLY WANT TO INTERACT WITH THE CORRESPONDING GOVERNMENTAL AUTHORITY IN THE U.S. THERE'S A NEED TO DEVELOP A SYSTEM OF INFORMATION COORDINATION REGARDING PRODUCT ACCEPTANCE AND CONFORMITY ASSESSMENT MECHANISMS, BOTH IN THE EC AND THE U.S. CERTAIN

INTERACTIONS AND NEGOTIATIONS WILL AND SHOULD INVOLVE U.S. GOVERNMENT PARTICIPATION.

IN THE NON-REGULATED AREAS, THE EC HAS INDICATED A WILLINGNESS TO WORK WITH THE ORGANIZATIONS IN THE PRIVATE SECTOR. ALSO, THE CREATION OF THE EUROPEAN ORGANIZATION FOR TESTING AND CERTIFICATION (EOTC), AS A PRIVATE SECTOR ENTITY, ALLOWS FOR INTERACTION OF VARIOUS INDUSTRY SECTOR COMMITTEES WITH THEIR COUNTERPARTS IN THE U.S. IN ADDITION, EOTC COULD PROVIDE FOR THE PARTICIPATION OF U.S. TESTING AND CERTIFICATION ORGANIZATIONS WHICH HAVE BILATERAL AGREEMENTS, MEMORANDA OF UNDERSTANDING (MOU'S), OR SUB-CONTRACTING AGREEMENTS WITH THE EUROPEAN BODIES, TO PARTICIPATE IN THE APPROVALS GROUPS OF EOTC.

THE KEY QUESTIONS IS: WILL THE U.S. TEST LABORATORIES BE ACCEPTED FOR SOME ROLE THAT WILL ASSIST U.S. MANUFACTURERS IN GETTING ACCEPTANCE OF THEIR PRODUCTS IN EC?

THE CURRENT INFORMATION INDICATES THAT NOTIFIED BODIES CAN ONLY EXIST IN EC MEMBER STATES. IN REGULATED AREAS, THIRD-COUNTRY AGREEMENTS, MOU'S OR SUB-CONTRACTING ARRANGEMENTS INVOLVING THESE NOTIFIED BODIES MUST BE APPROVED BY THE EC ITSELF. THERE ARE NO PROVISIONS, AT LEAST AT PRESENT, TO RECONGIZE EXTERNAL ACCREDITATION PROGRAMS SUCH AS THE ONE THAT HAS BEEN PROPOSED FOR THE U.S.

IN THE NON-REGULATED SECTOR, THE UMBRELLA EUROPEAN BODY WILL BE THE EOTC. ITS STRUCTURE AND OPERATING CRITERIA HAVE NOT BEEN FINALIZED AS YET, BUT IT IS LIKELY THAT THE EXISTING AND NEW ARRANGEMENTS WILL BE COORDINATED THROUGH THE EOTC.

DOES THIS MEAN THEN THAT MOST U.S. PRODUCED EC REGULATED PRODUCTS, AND PERHAPS EVEN SOME NON-REGULATED PRODUCTS, WILL HAVE TO BE TESTED AND CERTIFIED IN EC COUNTRIES IN ORDER TO BE SOLD THERE?

MAYBE NOT. THERE IS A GOOD LIKELIHOOD THAT METHODICALLY DEVELOPED RECIPROCAL AGREEMENTS BETWEEN THE U.S.LABORATORIES AND THEIR EUROPEAN COUNTERPARTS CAN BE CONSUMMATED JUST AS

THE PAST. THIS WILL PERMIT TESTS AND DATA PACKAGES DEVELOPED BY ONE LAB TO BE CONFIDENTLY ACCEPTED BY ANOTHER.

WHERE UL HAS BEEN INVOLVED, THESE ARRANGEMENTS HAVE INCLUDED CROSS-TRAINING OF STAFF, INITIAL SIMULTANEOUS WITNESSING OF TESTS, ROUND-ROBIN TESTING AND OTHER MEASURES TO ASSURE UNIFORMITY. THIS ASSURANCE CANNOT BE OBTAINED IN A SIMPLISTIC APPROACH INVOLVING A LABORATORY ACCREDITATION SCHEME, EVEN ONE MANAGED BY A GOVERNMENT AGENCY.

THIS TYPE OF APPROACH WILL ALLOW U.S. DEVELOPED TEST WORK AND DATA PACKAGES TO BE ACCEPTED IN THE EC CONFORMITY ASSESSMENT PROCESS EVEN WITHOUT THE OFFICIAL "NOTIFIED BODY" STATUS. IT IS IMPORTANT, ONCE AGAIN, TO EMPHASIZE THAT THE SPECIFIC CRITERIA FOR APPROVAL BY THE EC OF BILATERAL TEST EXCHANGE AGREEMENTS OR SUB-CONTRACTING AGREEMENTS ARE YET NOT KNOWN. CERTAINLY, THE TECHNICAL

COMPETENCE OF THE NON-COMMUNITY ORGANIZATIONS WILL LIKELY BE DETERMINED THROUGH EN 45,000 SERIES STANDARDS. ADDITIONALLY, GUARANTEES PROVIDED BY AND BENEFITS FLOWING TO THE AGREEMENT PARTIES WILL HAVE TO BE ASSESSED BY EC. IT IS LIKELY THAT FOR PRODUCTS NOT REGULATED BY THE EC, EXISTING OR NEWLY DEVELOPED AGREEMENTS WILL NOT BE SUBJECT TO EC REVIEW AND APPROVAL BUT INSTEAD WILL BE COORDINATED THROUGH EOTC.

WHILE THESE DEVELOPMENTS CLEARLY INDICATE A NEED FOR COORDINATION OF TESTING AND CERTIFICATION MECHANISMS, IT IS NOT MANDATORY THAT THIS COORDINATION TAKE PLACE IN THE GOVERNMENTAL ARENA. NOR IT IS ESSENTIAL THAT A U.S. BASED ACCREDITATION PROCESS BE A PART OF THIS COORDINATION. AS A MATTER OF FACT, IF IT IS TO BE COMPATIBLE WITH THE MAJORITY OF PRIVATE SECTOR PROGRAMS IN THE E.C., THE COORDINATION EFFORT SHOULD RESIDE IN THE VOLUNTARY, MARKET DRIVEN PRIVATE SECTOR, AS IS THE EOTC.

AS NOTED EARLIER, AN EFFECTIVE AND COMPREHENSIVE ACCREDITATION PROGRAM FOR TESTING AND CERTIFICATION ORGANIZATIONS WILL BE EXTREMELY EXPENSIVE. BEFORE EMBARKING ON A NATIONAL PROGRAM OF THIS TYPE, IT MUST BE DETERMINED WHETHER APPROVAL THROUGH SUCH A PROCESS, BASED IN THE U.S., WILL BE ACCEPTABLE TO THE EC AND OTHERS. AND, IF SUCH A PROCESS IS CONSIDERED ACCEPTABLE, FROM A PRACTICAL STANDPOINT, WHAT WILL IT MEAN TO U.S. INTERESTS?

QUID PRO QUO

A KEY QUESTION TO CONSIDER IS: IN RETURN FOR EASIER ACCESS, WHAT DEMANDS MIGHT BE PLACED ON U.S. CERTIFIER, REGULATORY AUTHORITIES AND OTHERS?

THE U.S. SAFETY SYSTEM IS A REASONABLLY WELL ORGANIZED NETWORK OF CODES, STANDARDS, CERTIFICATIONS AND GOVERNMENTAL ENFORCEMENT ENTITIES. IT IS A SYSTEM THAT HAS WORKED FOR NEARLY ONE-HALF A CENTURY. FOR EXAMPLE, THE NATIONAL ELECTRICAL CODE (NEC) IS ADOPTED INTO LAW BY MOST OF THE STATES AND MUNICIPALITIES AND IS ENFORCED BY OVER 15,000 ELECTRICAL INSPECTORS AND OTHER AUTHORITIES THROUGHOUT THE COUNTRY. THESE INSPECTORS AND AUTHORITIES RELY ON THIRD-PARTY CERTIFICATIONS FOR PRODUCT SAFETY PERFORMANCE CONFORMITY. PRODUCT REQUIREMENTS ARE CONTAINED IN PUBLISHED PRODUCT AND INSTALLATION STANDARDS, MANY OF WHICH ARE LEGALLY AND/OR LEGISLATIVELY MANDATED.

NOW, SUPPOSE THE U.S. PUSHES FOR ACCEPTANCE OF TEST DATA AND/OR PRODUCT CERTIFICATIONS FROM U.S. ORGANIZATIONS BY THE EC. ALSO SUPPOSE U.S. ORGANIZATIONS SEEK TO BE DESIGNATED AS "NOTIFIED BODIES", AS SOME HAVE.

THE EC, ITS MEMBER STATES, EUROPEAN NOTIFIED BODIES, AND OTHER ENTITIES, WILL MOST CERTAINLY DEMAND A QUID PRO QUO. THIS WOULD MEAN THAT PRODUCTS CERTIFIED BY ALL NOTIFIED BODIES IN EUROPE - TWELVE, TWENTY, FIFTY OR HUNDREDS OF SUCH BODIES - MUST BE ACCEPTED IN THE U.S. BY FEDERAL, STATE, AND MUNICIPAL AUTHORITIES, AS WELL AS TESTING AND CERTIFICATION ORGANIZATIONS.

WILL THESE PRODUCTS BE EVALUATED IN ACCORDANCE WITH U.S. PRODUCT AND INSTALLATION STANDARDS AND CODES? IF SO, HOW WILL EUROPEAN ORGANIZATIONS KEEP UP WITH THESE STANDARDS? WILL U.S. INDUSTRIES HAVE TO MEET WITH ALL OF THESE EUROPEAN ORGANIZATIONS TO DISCUSS IMPLEMENTATION PROCEDURES AND INTERPRETATIONS? A GREAT DEAL OF TIME IS SPENT BY U.S. INTERESTS ALREADY WITH THE FEW CERTIFYING LABORATORIES IN THE U.S. IN ORDER TO MAINTAIN UNIFORMITY, INTERPRET STANDARDS, RESOLVE DISPUTES, DRAFT OPERATING

POLICIES, AND CARRY ON THE COMMUNICATION REQUIRED TO CONTINUE A FAIR AND UNDERSTANDABLE PRODUCT EVALUATION AND CERTIFICATION SYSTEM. DOES IT SEEM PRACTICAL OR EVEN POSSIBLE TO INTERACT WITH ALL THE NOTIFIED BODIES IN EC AND OUTSIDE? HARDLY!

CONSIDER FOR A MOMENT, JUST ONE U.S. PRODUCT SECTOR -- ELECTRICAL PRODUCTS. THESE PRODUCTS ARE DESIGNED TO BE INSTALLED AND TO PERFORM IN ACCORDANCE WITH THE NEC. THE NEC IS DEVELOPED BY PANELS OR COMMITTEES IN WHICH INDUSTRY, CERTIFIERS, AND REGULATORS ARE AMPLY REPRESENTED, TOGETHER WITH ELECTRICAL EXPERTS, CONTRACTORS, AND OTHERS. WILL A MANUFACTURER OR A LABORATORY IN A SMALLER EC COUNTRY OR A FOREIGN NATION, WITH NO INVOLVEMENT WITH THE NEC, UNDERSTAND AND CORRECTLY APPLY THIS COMPLEX CODE? HARDLY!

HOW ABOUT THE LEGAL AND JURISDICTIONAL PROBLEMS FOR ELECTRICAL INSPECTORS AND OTHER U.S. AUTHORITIES WHOSE RESPONSIBILITY IT IS TO ACCEPT OR REJECT AN ELECTRICAL DISTRIBUTION SYSTEM AND ALL OF ITS COMPONENTS?

FRANKLY, THE ADOPTION OF A PROCEDURE WHICH WOULD REQUIRE THE U.S. TO CHANGE ITS ENTIRE SYSTEM FOR PRODUCT ACCEPTANCE AND ENFORCEMENT RESPONSIBILITIES IS OVERWHELMING AND IS SIMPLY NOT LIKELY TO HAPPEN. NOR SHOULD THERE BE A COMPROMISE IN THE LEVELS OF SAFETY IN PRODUCTS THAT ARE BROUGHT INTO THIS COUNTRY, MERELY TO ACHIEVE RECIPROCITY.

WHAT MUST BE REMEMBERED IS THE TERM "EQUAL ACCESS" AS OPPOSED TO "IDENTICAL SYSTEMS". HEREIN LIES THE KEY TO PRODUCT ACCEPTANCE IN A GLOBAL ENVIRONMENT. IT IS NOT NECESSARY THAT THE U.S. SYSTEM BE CHANGED TO ACCOMMODATE THE EUROPEAN SYSTEM, NOR THAT THE EUROPEAN SYSTEM BE CHANGED TO ACCOMMODATE THE U.S. SYSTEM. RATHER, EQUAL ACCESS THROUGH

BILATERAL AGREEMENTS BETWEEN THE U.S. AND EC ORGANIZATIONS, COUPLED WITH THE ACCEPTANCE OF COMPARABLE PRODUCT TESTING AND CERTIFICATION DATA PACKAGES AND INCLUDING THE RIGHT OF REJECTION AND SUPPLEMENTAL VERIFICATION TESTING, MUST BE PURSUED.

IT SHOULD BE NOTED HERE THAT THESE DATA PACKAGES WOULD BE EXPECTED TO CONTAIN THE REQUIRED STANDARD COMPLIANCE REPORTS, FACTORY QUALITY ASSURANCES, AND APPROPRIATE LABORATORY PRACTICE STATEMENTS. THIS APPROACH WILL REQUIRE THE DEVELOPMENT OF APPROPRIATE U.S. CRITERIA COMPARABLE TO THE EC GLOBAL APPROACH TO CONFORMITY ASSESSMENT ADOPTED BY THE COUNCIL OF MINISTERS LAST DECEMBER. APPLICATION OF THESE EQUAL ACCESS APPROACHES COULD EVENTUALLY PERMIT PRODUCT TESTING AND CERTIFICATIONS TO SPECIFIED STANDARDS TO BE ACCEPTED IN THE EC, THE U.S., OR OTHER COUNTRIES WITHOUT "NOTIFIED BODY" STATUS.

A RECENT GENERAL ACCOUNTING OFFICE (GAO) STUDY ON THE EC INDICATES THAT BOTH THE U.S. GOVERNMENT AND PRIVATE SECTOR REPRESENTATIVES HAVE EXPRESSED CONCERN ON WHETHER THE U.S. IS READY TO EXTEND EVEN THE BILATERAL AGREEMENTS THAT ARE CURRENTLY IN PLACE WITH ONE MEMBER STATE TO THE OTHER ELEVEN. THE STUDY INDICATES THAT THE COMPETENCE OF THE CERTIFICATION BODIES IN THE OTHER EC COUNTRIES WILL NEED TO BE DETERMINED BEFORE AGREEMENTS CAN BE EXTENDED - EC-WIDE. U.S. INDUSTRY AND BUSINESS ASSOCIATION OFFICIALS HAVE RECENTLY EXPRESSED CONCERN OVER WHETHER THE U.S. CAN OR WOULD WANT TO PROVIDE RECIPROCAL ACCESS.

IS AMERICAN INDUSTRY WILLING TO PUT UP WITH COMMERCIAL DIFFERENTIALS? IN OTHER WORDS, COMPETE AT THE SAME PRICE FOR PRODUCTS PRODUCED TO DIFFERENT SETS OF TECHNICAL SPECIFICATIONS AND CODES WHICH HAVE BEEN VALIDATED BY FOREIGN ENTITIES. WHAT WILL BE THE BURDEN ON OUR

JURISDICTIONAL AUTHORITIES AT THE FEDERAL, STATE AND LOCAL LEVELS WHO ARE, BY OUR OWN LAWS, CHARGED WITH THE RESPONSIBILITIES OF PROTECTING PUBLIC LIFE, PROPERTY AND THE ENVIRONMENT? WHAT CAN CONSUMERS EXPECT? WILL THE SAFETY LEVELS PROVIDED AND EXPECTED IN OUR NATION BECOME COMPROMISED? I HOPE NOT.

CLEARLY, THESE QUESTIONS MUST BE CONSIDERED AND THE ANSWERS ANALYZED BEFORE EMBARKING ON A U.S. STRATEGY FOR OPERATING IN THE EC.

U.S. OBJECTIVES

THE PRIMARY U.S. STRATEGY OUGHT TO BE TO ACHIEVE THE OBJECTIVE OF FAIR TRADE VIA EQUAL AND COMPETITIVE ACCESS TO EC MARKETS BY U.S. MANUFACTURERS. IN THIS REGARD, THE FOLLOWING KEY ELEMENTS AND INITIATIVES CAN BE USED IN FORMULATING THE OVERALL U.S. STRATEGY:

1. INTERNATIONAL NEEDS WILL DIFFER FROM INDUSTRY TO INDUSTRY, AND THUS INPUT FROM THE APPROPRIATE U.S. INDUSTRY SECTOR SHOULD BE STRONGLY CONSIDERED BEFORE EMBARKING ON A U.S. STRATEGY RELATIVE TO TESTING, CERTIFICATION AND QUALITY ASSESSMENT PROCEDURES.

2. ESTABLISH MECHANISMS IN GOVERNMENT AND PRIVATE SECTORS TO MONITOR, UNDERSTAND, AND, WHERE NECESSARY, IMPACT THE EC DEVELOPMENTS AND PROCEDURES, ESPECIALLY THOSE RELATING TO THIRD COUNTRIES.
3. SEEK EQUAL AND COMPETITIVE ACCESS TO EC TESTING AND CERTIFICATION PROGRAMS FOR U.S. MANUFACTURERS.
4. PROMOTE PRODUCT CATEGORY AND STANDARDS SPECIFIC TEST DATA EXCHANGE PROCEDURES, SUBCONTRACTING ARRANGEMENTS AND BILATERAL AGREEMENTS RATHER THAN GENERIC ACCREDITATION AND ACCEPTANCE SCHEMES.
5. HARMONIZE U.S. STANDARDS WITH INTERNATIONAL STANDARDS TO THE EXTENT PRACTICABLE, AND AS NEEDED, BY THE AFFECTED INDUSTRY.

6. PROMOTE THE FACT THAT IT IS NEITHER NECESSARY NOR PRACTICAL TO HAVE IDENTICAL STANDARDS, TESTING AND CERTIFICATION SYSTEMS IN ALL NATIONS. RATHER, THE IMPORTED PRODUCTS SHOULD BE AFFORDED ACCESS TO CONFORMITY ASSESSMENT PROCEDURES EQUIVALENT TO THOSE ENJOYED BY THE DOMESTIC PRODUCERS.

7. DEVELOP BILATERAL AGREEMENTS, SUBCONTRACTING ARRANGEMENTS AND MOU'S BASED ON TECHNICAL COMPETENCE AND METHODICAL AND LOGICAL PROCEDURES TO ENSURE UNIFORMITY OF TEST RESULTS AND PRODUCT EVALUATIONS.

UL IS READY TO WORK WITH AND ASSIST THE U.S. CONGRESS, THE FEDERAL GOVERNMENT, AS WELL AS ORGANIZATIONS IN THE PRIVATE SECTOR, TOWARD ACHIEVING THE ULTIMATE OBJECTIVE OF FAIR TRADE AND EQUAL ACCESS TO ALL THE MARKETS.

THANK YOU

S. JOE BHATIA

VICE PRESIDENT - GOVERNMENTAL AFFAIRS

UNDERWRITERS LABORATORIES

Mr. Bhatia has been with Underwriters Laboratories for the past nineteen years. He holds a Bachelor's Degree in Electrical Engineering and a Master's Degree in Industrial Management.

Mr. Bhatia's responsibilities including working with Congress, Government agencies, trade associations, and other organizations regarding UL's programs, policies, and procedures.

In his tenure at UL, Mr. Bhatia has served in various capacities including positions in the Engineering Department, assignments to the Research and Technology Development Department; leading teams that conducted the feasibility studies of UL's involvement in electromagnetic interference *(EMI)*, *telecommunications*, *fiber* optics, and satellite, microwave and cable transmission.

He is a registered safety engineer and serves on various committees for the American National Standards Institute (ANSI), and the Institute of Electrical and Electronic Engineers, the American Society of Electroplated Plastics and others. He is a member of the Standards Engineering Society, National Fire Protection Association, Pi Mu Epsilon and the American Management Association.

Mr. Bhatia and his wife, Punita, reside in McLean, Virginia and have two sons.

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Mr. **Valentine**. Mr. Frier.

Mr. **Frier**. Mr. Chairman, my name is Leonard Frier, and I'm president of MET Electrical Testing Company, a small independent electrical testing laboratory in Baltimore, MD. And I'm also chairman of the American National Standards Institute's Committee, number Z34. I appreciate the opportunity to testify before this committee and to make the critical issues of testing and certification and how it relates to manufacturers, to trade, in this area.

The Z34 Committee is the only accredited committee in the United States writing standards on principles underlying valid certification and labeling of products and services. My work with this committee has allowed me to become involved with many organizations, associations, manufacturers, certain government agencies and individuals who need or are part of a certification process. For some, the existing certification system in the United States is working fine. However, for many, it is a hindrance. The Z34 Committee is working very hard to develop a standard for certification that satisfies the needs of the majority and is beneficial for the United States. We are also trying to harmonize our standard with all comparable international standards on certification.

It is hard to comprehend that this committee is trying to accomplish in the private sector exactly what the EC Commission, a government agency in Europe, is doing. Theoretically, the government agency operates in the general interest of the community, while in the private sector each participant has a specialized interest. For something of this major a magnitude, this may not be good. I am happy to report that on this issue that the committee is very well balanced in its representation and progress is moving forward.

All of the items in the committee's objective can be accomplished and, indeed, most of it is already in place. But first, standards and their harmonization with international standards is not, in my opinion, an issue which needs addressing in order to provide United States producers the ability to sell their products or services anywhere in the world. There are too many conflicting conditions which cannot be harmonized. The different voltages of appliances in homes, for example, can never be the same in Europe and in the United States. Which country would be willing to throw out all their appliances or rewire their homes to accept these different voltages?

The issue and, in my opinion, the only issue is testing and certification. The most difficult item to accomplish in order to allow testing and certification to work has already been accomplished in the United States. Let me explain.

On products such as electrical, electro-mechanical, and electromedical devices, fire safety and such, a manufacturer needs some type of acceptable certification in most countries in the world, especially in the United States. In other countries, the enforcement of policies regarding certification and identification of products which comply with the applicable safety requirement is under some type of government authority or control. In the United States, the determination that a product complies with a particular requirement was under no control and the enforcement of the requirements for that product to be identified as complying was done by individual inspection authorities throughout the United States. This meant that many manufacturers had to deal with over 2,000 different authorities. It is for this reason that the Europeans called us the "Star Spangled Banner to Trade."

Now the Occupational Safety and Health Administration has accepted a regulation which allows laboratories to receive accreditation, and they do have the ability to preempt states for that area. That one major problem, an obstacle in electrical products, has been resolved.

In 54 countries in the world, large and small, there is a national certification mark, and now the European Community has a mark. It is the CE mark. This is a major item for world trade. In every major country, it is a national mark. However, in the United States, it is many marks. This must be changed.

Presently, if a manufacturer is to sell products to the 320 million people in the EC after 1992, what can the U.S. give? The answer is nothing, and that is ridiculous. The Europeans have the ability to allow a manufacturer or producer to place a CE mark on a product and this product can be sold and will be accepted anywhere in Europe. This includes food, chemicals, pharmaceuticals, and electrical products. Japan can do the same thing, and so can over 50 other countries. The United States is not one of them. The United States needs to be. Unfortunately, the sounds emanating from the testing and certification group is either very quiet or is being drowned out by dominant forces that the present status quo condition exists.

Here's what has to happen. The U.S. Trade Representative has to have the ability to sit with counterpart government officials in other countries and say: we will give your suppliers of products or services the ability to sell these products anywhere in the United States, provided they are manufactured and certified to comply with U.S. laws and standards, if you provide U.S. manufacturers this same ability in your country.

Actually, this is reciprocity. This is what the Europeans have been saying and so have so many others. Before now, the U.S. Trade Representative or, indeed, Congress, could not say it. Before no one had the authority to accept an electrical product or medical diagnostic device except the inspection authority in that jurisdiction where the device would be installed. These municipal inspectors reported to no one, and unless Congress wanted to preempt state jurisdictional authority, this is the way it was.

Now, with OSHA accrediting laboratories, and inspection authorities being required to accept OSHA standards, the major stumbling block to having a system which could provide reciprocity to other countries in the world has been removed.

The last remaining requirement then is a United States certification mark. This mark should exist on food products, medicines, electrical products, mechanical products, or any item which must go through certification to assure that a product was produced to an American standard and that the product complied with that standard. The United States certification mark would place the United States on par with all other trading partners. The mark is very significant for trade in the United States. Like the Good Housekeeping seal of approval, you as a consumer look for the mark because, with this, you have some confidence. U.S. Department of Agriculture inspectors look for this mark when they inspect stores. Building inspectors look for the mark when they inspect equipment or materials on new construction. The mark is the symbol that the product met some type of requirement and someone has identified the product as meeting the requirement.

For certain electrical or electro-medical, mechanical items and the like, many foreign manufacturers felt that in order to sell their product in the United States, they had to give a blank check to someone who could supply the acceptable mark.

The mark has to exist to facilitate trade. On many products a tiny mark is the only possible method of identifying everything which needs to be said about the product. There is a very good standard in the United States which describes all of the requirements that must be present before a product can receive the mark. Many of the requirements are enforced by Federal agencies, but for the most part, all of the requirements, standards and organizations which apply a mark or some other means to indicate a product complies with a standard are in the private sector. I strongly feel it should all stay in the private sector, with oversight. With oversight, the issue of testing and certification could be resolved.

I propose that Congress charter a corporation for the sole purpose of administering a United States certification mark. This corporation would license entities to apply the U.S. certification mark on products when it has been determined that these products meet all the requirements for certification.

The standard which would determine that a product or service could be entitled to receive the U.S. certification mark is the American National Standards Institute, ANSI, Z34 standard. This standard sets the requirements for validation of third party certification programs. This standard has been adopted by the U.S. Government Agency for Interdepartmental Policy, and the standard requires a valid laboratory accreditation program which exists in most Government agencies at this time.

All that is left is the U.S. certification mark. Now everything is in the private sector, with exception of the many laboratory accreditation programs, but they are only accrediting private laboratories. Therefore, the oversight of the entire industry would come in with an organization, reporting to Congress, controlling the mark. Testing and certification would truly be a public/private partnership. I would suggest that the corporation be housed in an organization such as the American Council of Independent Laboratories, ACIL. This organization is an association of many testing laboratories and it appears they would have the infrastructure needed to administer the program.

Now, Mr. Chairman, I tried to apply additional testimony to respond to the focus of the hearing, which I have given out. I would like to continue with this, which has not been prepared. However, it was sent. What it does is, it sort of preproposes that a certification mark does exist. With that premise that the mark does exist, I would like to answer the six questions that are listed in the focus of the hearing.

The first question was, what is the impact of the lack of a U.S. focal point for testing and certification and so on. I say that there would be no lack of a U.S. focal point for testing and certification.

The U.S. certification mark corporation would be the proper, quasi-government agency to handle all issues for an identifiable mark. This would be the vehicle to identify that a product did comply with an applicable safety or performance standard and facilitate domestic and international trade.

Question number two, what type of organization, private or government, should be established to provide the effective mark. My answer is the U.S. certification mark corporation would be a quasi-government agency that would form a true poublic/private partnership. The relationship would provide an equitable means for all suppliers, producers or certifiers to gain access to U.S. markets. This agency would be involved with government negotiations of international trade agreements, thus assuring that no single U.S. company would be denied entry into foreign markets.

Question number three, it says what demands might be placed on U.S. certifiers. Demands would be removed from state and local regulatory authorities. The U.S. certification mark corporation would now be responsible for policing certification. Demands would also be removed from individual companies. With U.S. Government involvement, there would be negotiations between governments, not between private organizations and foreign governments—the condition that now exists. There would, however, be increased demands on ANSI, but that would provide equitable standards for the certification.

For questions number four through six, my response to these questions would be to propose a system and how it would actually work.

Actually, it's not new. If we copied the EC description of the CE mark in Europe and used it here, it would be perfect.

The U.S. certification mark corporation would only license the use of the mark to an organization that produced a product or service in strict accordance with the requirements of the American National Standard Z34. The Z34 Committee would have a certification or accreditation subcommittee under its authority to examine, monitor suppliers and producers of goods or services and assure that they complied with the requirements of Z34. When assurance is provided, the proper licensing agreement would be drafted with the USCM corporation. The producer of goods or services would pay a reasonable licensing fee based on items produced. The mark would apply to items such as food products, pharmaceuticals, electrical products and so on.

then the U.S. Trade Representative would sit with foreign representatives, government-to-government, which is exactly how it should be, and say: If our U.S. certification mark corporation determines that you have products or services that are produced in strict accordance with applicable United States standard, and this can be certified by an organization accredited by the appropriate U.S. agency, we will give you the ability to use the U.S. mark, provided you allow U.S. producers the ability to use your mark when they produce products in accordance with your standards and get them certified by an agency that has met your standards for a certification agency.

This is true reciprocity and only government representatives can negotiate to eliminate the trade barriers that exist.

Harmonization of standards should not be an issue. U.S. manufacturers should manufacture the products to the foreign standards and foreign manufactuers should manufacture to U.S. standards. Foreign laboratories should be accredited to U.S. standards by the applicable U.S. accrediting agency, and U.S. laboratories should be accredited by the appropriate foreign agency to their requirements.

Thank you very much, Mr. Chairman.

[The prepared statement of Leonard Frier, with attachment, follows:]

TESTIMONY
COMMITTEE ON SCIENCE AND TECHNOLOGY
FOR THE
FEDERAL ROLE IN INTERNATIONAL TESTING, CERTIFICATION AND QUALITY ASSURANCE

June 26, 1990

Gentlemen, my name is Leonard Frier. I am President of MET Electrical Testing Company, a small independent electrical testing laboratory in Baltimore. I'm also Chairman of the American National Standards Institute's Z34 Committee. I appreciate the opportunity to testify before this committee on the critical issue influencing the ability of United States manufacturers to trade and that is restrictions on Testing & Certification.

The Z34 Committee is the only accredited committee in the United States writing standards on principals underlying valid certification and labeling of products and services. My work with this committee has allowed me to become involved with many organizations, associations, manufacturers, certain government agencies and individuals who need or are part of a certification process. For some, the existing certification system in the United States is working fine. However, for many, it is a hinderance. The Z34 Committee is working very hard to develop a standard for certification that satisfies the needs of the majority and is beneficial for the United States. We are also trying to harmonize our standard with all comparable international standards on certification.

It is hard to comprehend that this committee is trying to accomplish in the private sector exactly what the EC Commission, a Government agency in Europe, is doing. Theoretically, the government agency operates in the general interest of the community, while in the private sector each participant has a specialized interest -- for something this major, this may not be good. I am happy to report on this issue that this committee has balanced representation; however, our progress is somewhat slow.

The Objective of this committee and the standard we are developing is attached.

All of this can be accomplished and, indeed, most of it is already in place. First, standards and their harmonization with international standards is not, in my opinion, an issue which needs addressing in order to provide United States producers the ability to sell their products or services anywhere in the world. U.S. producers will have to provide products or services in accordance with the standards of other countries, just like foreign producers will have to provide products or services in accordance with our standards and laws. There are too many conflicting conditions which cannot be harmonized. The different voltages of appliances in homes, for example, can never be the same in Europe and the United States. Which country would be willing to throw out all their appliances or rewire their homes to accommodate the different voltages.

The real issue and, in my opinion, the only issue is testing and certification. The most difficult items to accomplish in order to allow testing and certification to work have already been accomplished in the United States. Please let me explain:

On products such as electrical, electro-medical, electro-mechanical, fire safety and such, a manufacturer needs some type of acceptable certification in most countries in the world, especially in the United States. In other countries, the enforcement of policies regarding certification and identification of products which comply with the applicable safety requirement is under some type of Government authority or control. In the United States, the determination that a product complies with a particular requirement was under no central control and the enforcement of the requirement that the product be identified as complying was done by individual inspection authorities throughout the United States. This meant that many manufacturers had to deal with over two thousand different authorities. It is for this reason that the Europeans called us the STAR SPANGLED BANNER BARRIER TO TRADE.

Except for the Occupational Safety and Health Administration (OSHA), no other Federal Government Agency has the authority over individual inspection authorities. This is the only agency which can preempt a State regarding which products can and cannot be used in a jurisdiction, but only in the work place. OSHA promulgated a rule which is now in effect and which puts controls on a certification agency and requires that individual jurisdictions accept these certifications on certain products. It has taken some time for this to take hold, but it is progressing. The major significance of this is that, for the first time, a foreign Government can talk to the U.S. Government on the issue of certification. Before, that was impossible. Can you imagine the U.S. Government only being able to speak to a private group of individuals in another country on Government issues?

In fifty-four countries in the world, large and small, there is a national certification mark and now the European Community has a mark -- it is the CE mark. This is a major item for world trade. In every major country, it is a National Mark; however, in the United States, it is many marks. This must be changed. Presently, if the United States negotiates with the Europeans and wins a major concession to allow U.S. manufacturers to sell certain products to the 320 million people in the EC after 1992, what can the U.S. give? The answer is "nothing" and that is ridiculous. The Europeans have the ability to allow a manufacturer or producer to place a CE mark on a product and this product can be sold and will be accepted anywhere in Europe. This includes: food, chemicals, pharmaceuticals, and electrical products. Japan can do the same and so can over fifty other countries -- the United States is not one of them. The United States needs to be. Unfortunately, the sound emanating from the testing and certification group is either very quiet or is being drowned out by dominant forces from the present status quo that exists.

Here's what has to happen.... The U.S. Trade Representative has to have the ability to sit with counterpart government officials in other countries and say:

.....We will give your suppliers of products or services the ability to sell these products anywhere in the United States, provided they are manufactured and certified to comply with U.S. laws and standards if You provide U.S. manufacturers this same ability.

Actually this is RECIPROCITY. This is what the Europeans have been saying and so have many others. Before now the U.S. Trade Representative or, indeed, Congress could not say it. Before no one had the authority to accept an electrical product or medical diagnostic device except the inspection authority in that jurisdiction. These municipal inspectors reported to no one and unless Congress wanted to preempt state jurisdictional authority, this is the way it was.

Now with OSHA accrediting laboratories and inspection authorities being required to accept OSHA standards, the major stumbling block to having a system which can provide reciprocity to other countries in the world has been removed.

The last remaining requirement then is a United States certification mark. This mark should exist on food products, medicines, electrical products, mechanical products or any item which must go through certification to assure that the product was produced to an American Standard and that the product complied with the standard. The United States Certification Mark would place the United States on par with all of our other trading partners. The mark is very significant for trade in the United States. Like the Good Housekeeping seal of approval, you as a consumer look for the mark because with this you have some confidence. U.S. Department of Agriculture inspectors look for this mark when they inspect stores. Building inspectors look for a mark when they inspect equipment or materials on new construction. The mark is the symbol that the product met some type of requirement and someone has identified this product as meeting the requirement.

For certain electrical or electro-medical, mechanical items and the like, many foreign manufacturers felt that in order to sell their product in the United States, they had to give a blank check to someone who could supply the acceptable mark.

The mark has to exist to facilitate trade. On many products a tiny mark is the only possible method of identifying everything which needs to be said about the product. There are very good standards in the United States which describe all of the requirements that must be present before a product can receive a mark. Many of the requirements are enforced by federal agencies, but for the most part, all of the requirements, standards and organizations which apply a mark or some other means to indicate a product complies with a standard are in the private sector. I strongly feel it should all stay in the private sector -- with OVERSIGHT. With Oversight, the issue of Testing and Certification could be resolved.

I propose that Congress charter a Corporation for the sole purpose of administrating a United States Certification Mark. This corporation would license entities to apply the U.S. Certification mark on products when it has been determined that these products met all the requirements for certification.

The standard which would determine that a product or service could be entitled to receive the U.S. certification mark is the American National Standards Institute (ANSI) Z34. This standard sets the requirements for validation of third party certification programs. The standard has been adopted by the U.S. Government Agency for Interdepartmental Policy. The standard requires a valid laboratory accreditation program which exists in most Government agencies at this time.

All that is left is the U.S. Certification Mark. Now everything is in the private sector, with exception of the many laboratory accreditation programs, but they are only accrediting private laboratories. Therefore, the Oversight of the entire industry would come in with an organization, reporting to Congress, controlling the mark. Testing and Certification would truly be a public/private partnership. I would suggest that the Corporation be housed in an organization such as the American Council of Independent Testing Laboratories. This organization is an association of many of the testing laboratories and it appears that they would have the infrastructure needed to administer the program.

Supplemental Testimony to Science and Technology Subcommittee Addressing the "Focus of Hearing" Questions

by

Leonard Frier, President

MET Electrical Testing Company, Inc.

A proper supplement to my testimony would be to address each item in the "focus of hearing" statements. To do this, I am starting with the premise that a U.S. Certification Mark and a U.S. Certification Mark Corporation exist.

1. There would be no lack of a U.S. focal point for testing and certification. The U.S. Certification Mark Corporation would be the proper Quasi-Government agency to handle all issues for an identifiable mark. This would be the vehicle to identify that a product did comply with an applicable safety or performance standard and would facilitate domestic and international trade.

2. The U.S. Certification Mark Corporation would be a Quasi-Government agency that would form a true public/private partnership. The relationship would provide an equitable means for all suppliers, producers or certifiers to gain access to U.S. markets. This agency will be involved with government negotiation of international trade agreements thus assuring that no single U.S. company would be denied entry into a foreign market.

3. Demands would be removed from state and local regulatory authorities. The U.S. Certification Mark Corporation would now be responsible for policing certification. Demands would also be removed from individual companies. With U.S. Government involvement there would be negotiations between governments, not between private organizations and foreign governments -- the condition that now exists. There would, however, be increased demands on ANSI, but it would provide equitable standards and certification.

4-6. My response to questions four to six is to describe how the proposed system will work. Actually, it is not new. If we copied the EC description of the CE mark in Europe and used it here, it would be perfect.

The U.S. Certification Mark Corporation would only license the use of the mark to an organization that produced a product or service in strict accordance with the requirements of The American National Standard Z34 committee. The Z34 committee would have a certification or accreditation subcommittee under its authority to examine and monitor suppliers and producers of goods or services and assure that they complied with the requirements of Z34. When assurance is provided, the proper licensing agreement would be drafted with the USCM Corp. The producer of goods or services would pay a reasonable licensing fee based on items produced. The mark would apply to items such as food products, pharmaceuticals, electrical products, etc.

Then the U.S. Trade Representative would sit with foreign representatives, government to government, which is exactly how it should be, and say:

If our U.S. Certification Mark Corporation determines that you have products or services that are produced in strict accordance with applicable United States standards and this can be certified by an organization accredited by the appropriate U.S. agencies, we will give you the ability to use the U.S. mark... provided you allow U.S. producers the ability to use your mark when they produce products in accordance with your standards and get them certified by an agency that has met your standards for a certification agency.

This is true reciprocity and only government representatives can negotiate to eliminate trade barriers.

Harmonization of standards should not be an issue. U.S. manufacturers should manufacture the products to the foreign standards and foreign manufacturers should manufacture to U.S. standards. Foreign laboratories should be accredited to U.S. standards by the applicable U.S. accrediting agency and U.S. laboratories should be accredited by the appropriate foreign agency to their requirements.

6/26/90

MET

BIOGRAPHY OF LEONARD FRIER

- Registered Professional Engineer in the State of Maryland
- President of MET Electrical Testing Company, a relatively small independent electrical testing laboratory in Baltimore, Maryland
- Chairman of the American National Standards Institute's Z34 Committee
- Active with the American Council of Independent Laboratories
- Member of:

  American National Standards Institute
  National Electrical Testing Association
  National Society of Professional Engineers
  American Society of Testing and Materials

  and other organizations which directly effect the testing and certification industry in the United States.
- Actively promotes independent testing and is a major "mover" in recognizable and acceptable methods of accreditation of testing laboratories.

Mr. **Valentine**. Thank you, sir.

Mr. Locke?

Mr. **Locke**. Chairman Valentine, thank you for the opportunity to make this statement. I am the President of the American Association for Laboratory Accreditation, and for simplification, we call it A2LA. It's a professional society, and strictly for the purpose of recognizing competent testing laboratories. That's our role.

I would like to address the issues in three general areas: laboratory testing and data, manufacturing quality system registration, and product certification. There's a tendency, it seems to me, that some of these get kind of all lumped together, and I would like to see if I can sort them out.

First of all, in laboratory accreditation, we're talking here about testing, testing products or testing environments or testing all kinds of materials, and so laboratory accreditation is dealing with the competence of a laboratory to do testing. That doesn't mean that the product will be accepted. It simply means that the tests are competent, are good tests that we can rely on to make decisions.

There are some levels of reciprocity going on in testing; that is, right now some tests would be accepted in one country that are done in another country. And typically, if the laboratories are accredited, then, in fact, this facilitates the acceptance of test data. So that's, in a sense, the testing function.

In the United States we have a plethora of laboratory accreditation agencies. We are probably the broadest and encompass more areas, I think, than any other in the private sector. Our direct competitor is the NVLAP program at NIST, so we have government involvement in the work that we do.

We have been negotiating with, or discussing with, the Europeans about the ability to have our laboratories accepted as accredited laboratories in Europe, trying to establish a relationship agreement, a memorandum of understanding, if you will. We've had a number of visits from foreign laboratories; we've also visited foreign laboratory accreditation systems; and their assessment process.

What we find at the moment is that laboratory accreditation systems in Europe are pretty much government-dominated, and that these government agencies are primarily single agencies, and these agencies are having trouble trying to figure out how to deal with the U.S. market. If they would have a memorandum of understanding with us in the private sector, then they would wonder how many more of these private sector organizations are they going to have to deal with and how is that all going to come about. So, with our limited resources, they simply find it difficult to get to all of the laboratory accreditation systems.

We've had good discussions with the British. By the way, the NAMAS system in the U.K. does not now have agreement with NIST. It doesn't have an agreement with anyone. They're waiting for their European Organization for Trade, EOTC, to decide what would be the relationship between laboratory accreditation systems in Europe and those in other parts of the world.

We do have an agreement with the Hong Kong Government laboratory accreditation system, so we do have an opportunity—we have had an opportunity to deal with governments in other countries. By the way, the Hong Kong system is a very good system. It's been accepted by NAMAS before the EOTC organization came about, so it has an MOU with NAMAS and also with us.

We have been also talking to the Italians, and there are some very strong interests and support for a possible agreement. We'd like to talk to many others, but again, for a small association to make all the connections, it becomes very difficult.

So if we talk about testing and recognition of test data, and actually the supplying of materials based on test data relative to that material, this is one area of trade that is quite significant.

There is another concept rapidly developing called quality system registration. This is significantly affecting commerce between suppliers of materials and component manufacturers in the United States. This concept goes beyond testing. It goes to the manufacturer of the material or component. We see here that European manufacturers are meeting requirements of quality registration systems over there, and one of the requirements is that their materials and suppliers should be under certain quality control, quality assurance concepts, that are covered by that registration.

So we see that some of our manufacturers are being affected by quality system registration. And a number of these manufacturers in the United States are trying to find ways that they can get their quality system registered.

There are evolving systems in the United States to do that. Of course, Underwriters Laboratories has one of the systems. The American Gas Association has a system. There is also an organization, the American Society for Quality Control, which is trying to develop a program to oversee the registrars, if you will, to see that the registrars are following the good quality practices. So a system in this quality system registration process is evolving, I think very rapidly.

There is a third concept which will we call product certification, about which we've heard particularly from UL today. It is a process where you provide a listing service so that a producer who makes a product can have UL oversee its production process, its design process, to obtain a listing. That listing then, essentially, is an indication that the manufacturing process for that product meets requirements. Now, this is on a product basis.

In practice, at least from what I can see, what's going on in Europe, the new developments over there tend to favor the extensive expansion of quality system registration and laboratory accreditation and not focus heavily on expansion of certification. That's reflected, I think, by some of the private sector efforts in this country to follow that trend.

Anyway, it's not a very simple picture, but when you talk about recognition, one needs to be aware of what part of the pie you're dealing with.

I attempted to come up with a possible model, and I looked back at some of the things that were successful in the United States in the past because it seems to me that whatever model we come up with needs to serve our domestic market first and, by the way, should be useful and should be effective enough to help us overseas.

I pointed to a national policy committee, the National Standards Policy Advisory Committee, which was formed over 11 years ago, by representatives of government, industry, societies and so on. It was sponsored basically by the American National Standards Institute, who basically paid for the effort, but did not control the effort. It was an effort that was done outside of the control of ANSI as a truly joint, cooperative effort between government and the private sector to come up with a policy for standards development.

I think this policy has served the community very well over the years. It did cause changes in ANSI, in the private sector development of standards; it caused changes in the government sector, notably with the Office of Management and Budget Circular A-119, which was a very significant development in government use of private sector standards.

We think that an ad hoc committee, similar to the NSPAC, should be established and implemented in order to develop a national policy on laboratory accreditation, quality system registration, and product certification.

The policy is what's missing. There is no policy. I think Mr. Frier talked about a policy which would be focused on a mark. What we need is a consensus organization that that comes up with a policy that gives us the guidelines that we can move ahead. This policy would require just a small effort. It could be done in reasonable time, but would be the basis for private sector or government sector organizations to revise their operations to get in harmony with this agreed-to policy.

Just briefly, in response to some of your points made, the impact of the lack of a U.S. focal point on trade. In the absence of a U.S. focal point, each U.S. system will have to go it alone, just as we are trying to go it alone. The larger entities with major resources they can bring to bear on the issues will find the going easier. But even now, some of them are seeking accreditation from the European organizations. So these very entities that could be the heart of our system are seeking to become accredited in Europe. So what makes up for a lack of U.S. policy turns out effectively to become part of the European policy, it seems to me.

Type of organization needed. An organization developed in the United States needs to provide a balance of interests. It goes almost without saying. It needs to be a coordinated body hosted by government with a private sector secretariat. Now, that model comes possibly from the EC itself, where the EOTC is a government operation and the secretariat is the major standards body CEN/CENELEC.

We believe that an ad hoc policy group—and I put some words together, but it sounds awfully long—should be established to develop a national conformance assessment policy. That's what we're talking about, national conformance assessment policy.

Demands placed on U.S. entities due to mutual recognition and reciprocity will be significant. I think in the situation today, and because the U.S. market is very flexible, these demands from Europe are really beginning to put pressures on the U.S. market to make the U.S. market available to foreign manufacturers, or to maximize that, and as a result, I think there are compromises that will be made in order to get into the European market, to compromises that may not be advantageous if we had a national policy we could refer to.

Government involvement will be necessary to gain acceptance. If a national conformance assessment policy is effective, then the roles of government and private sector organizations will be apparent and cooperation between government and the private sector based on these roles will bring acceptance by both the EOTC and EQS and the EC. I think this is pretty much what happened with the NSPAC, where we saw private and government sectors go about their work of putting their houses in order and effectively working together.

A question about whether a U.S. national mark is necessary. It's not all clear to us that the EC mark will be effective for the full scope of conformance options for which it's now envisioned. An EC mark can be put almost on anything by anybody. There needs to be some better concept of how the mark would apply and how it would work. Of course, that, I think, would fit within this policy that I think is needed.

The biggest problem we have at present in the United States is that no one has prepared a white paper, the vision, a role model or a policy which will serve to coalesce public opinion. I should say there are a number of visions, none of which is broad enough to serve as the national focal point. We recommend that the Congress consider authorizing and supporting with modest funds a distinguished panel to develop a national conformance assessment policy. This policy would not only guide government and private sector organizations in making changes to their operations to meet practices suggested by the policy, but wouid also set up a framework whereby both government and private sector organizations meeting these practices can earn national recognition.

Thank you very much.

[The prepared statement of John W. Locke follows:]

American Association For Laboratory Accreditation

STATEMENT OF JOHN W. LOCKE, PRESIDENT
AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION (A2LA)
BEFORE THE SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

ON THE FEDERAL ROLE IN INTERNATIONAL TESTING, CERTIFICATION, AND QUALITY ASSURANCE

JUNE 26, 1990

Chairman Valentine and Members of the Subcommittee:

Thank you for the opportunity to present the experiences of the American Association for Laboratory Accreditation (A2LA) in dealing with both domestic and international accreditation and quality requirements related to overseas markets.

We will address the following issues:

- Laboratory Testing and Test Data;
- Manufacturer Quality System Registration;
- Product Certification

We will conclude by responding to the questions which are the focus of this hearing.

A2LA BACKGROUND

I am John W. Locke, President of A2LA. I am here to express the view of the Association on these important trade policy matters. A summary of my personal background as related to this issue is included as Attachment 1 to this statement.

The Association is a nonprofit, nongovernmental, public service, membership society dedicated to the formal recognition of competent testing laboratories. We are organized in a manner similar to many of the voluntary consensus standards organizations. We do not develop test methods, relying instead on methods promulgated by our sister societies or by government agencies. Our requirements for accredited laboratories are ISO (International Organization for Standardization) Guide 25, "General Requirements for the Technical Competence of Testing Laboratories," and ISO Guide 38, "General Requirements for the Technical Acceptance of Testing Laboratories." The Association meets the requirements of the voluntary consensus standard, ASTM E994-84, "Guide for Laboratory Accreditation Systems" and similar requirements found in ISO Guides 54 and 55.

A Fact Sheet describing the Association is included as Attachment 2. Our Board of Directors is made up of representatives from government, major industries, laboratories and the public interest. The Vice Chairman is an employee of the National Institute of Occupational Safety and Health (NIOSH); other government representatives come from FDA and DOD, with ex-officio liaison members from EPA and NIST. As of June 20, 1990, we have accredited 236 laboratories in eight different fields of testing and we have an additional 60 laboratories in the process of being assessed. We have accredited laboratories in 34 states, Guam, and Canada.

In addition to our substantial accreditation activity, we have an active training program offering a variety of short courses on laboratory and system quality assurance and assessment (over 1000 students have attended in the past three years). Staffers participate as members of many other relevant national groups, including the Department of Commerce's Industry Functional Advisory Committee (IFAC-2) on Standards and Certification, the ANSI Certification Committee and International Certification Subcommittee, and the ASQC Technical Advisory Group on the International Standards Organization Technical Committee (TAG to ISO/TC 176) on Quality Assurance. We have negotiated an international agreement with the Hong Kong Government and are actively working on the establishment of international agreements with laboratory accreditation systems in Australia, Canada, France, Italy, New Zealand, and the United Kingdom.

LABORATORY TESTING AND ACCREDITATION

Laboratory accreditation is the formal recognition of the competence of a testing laboratory.

In the United States. There are, by some accounts, in excess of 130 laboratory accreditation systems, both public and private, functioning in the United States today. There is little coordination among these systems, in the private sector, in the public sector, or between public and private sectors. Many systems duplicate other accreditation systems. Most are narrow in focus, arising out of a specific need for resolving problems facing industry or government. Those who inquire find that locating and tracking which system does what can be time consuming, incomplete in satisfying needs, and even inaccurate. Often, industry, associations, government agencies, and individuals do not understand laboratory accreditation and its benefits. Thus, they do not know what system might serve their needs best. Complicating this is the manner in which the accrediting body is operated (the process) and the basis for structuring its service (its product). There are standards upon which to base both the process and the product. Some systems, such as A2LA, find their base in national and international standards, while others are rooted in narrower, specific industry or governmental standards. It is likely that lack of confidence in another system's ability to address what is considered "my area of expertise" is also at work. This can and does lead to much variability and cost for users of laboratory accreditation. All this suggests that we in the United States are not using our resources as effectively as we might.

There has been some successful cooperation between government and the private sectors in the medical area. For example, Congress has created laws which require that the Health Care Financing Administration recognize accreditations by nonprofit associations like A2LA. For a number of years, A2LA has tried to obtain similar recognition from government agencies. It has asked NIST to provide such recognition. However, as late as last November 20, 1989, Mr. Kammer, the then Acting Director of NIST, in testimony before this committee relative to the fastener legislation (H.R. 3000), specifically requested that the provision in H.R. 3000 that directs NIST to recognize accreditation systems such as ours, be deleted, ostensibly so that NIST would not be placed in a regulatory role over the private standards community. But NIST is effectively regulating all asbestos laboratories which perform tests in public schools for asbestos abatement projects. Over 75 percent of its accredited laboratories are in this regulatory role. In the meantime, A2LA has had to negotiate separately with individual government users, and has gained acceptance for use by DOD, certain environmental areas through EPA, and a few state and local governments. We have organized a yearly forum (held in May) to initiate cooperation among laboratory accreditation systems. However there doesn't seem to be an incentive for cooperation among systems, either in the government or in the private sector. Meanwhile, laboratories are being inundated with assessments from their users and users of accredited laboratories have no clear source of recognized accreditation systems which will make their task of finding a competent laboratory possible without actually adding to the laboratory assessment burden by doing their own assessments.

In Europe. Most laboratory accreditation systems are government organized. These government systems are not necessarily the only systems but they predominate. The largest ones have established Memoranda of Understanding (MOUs) with each other so that test data in accredited laboratories in one country is acceptable in the second. A2LA is actively negotiating with these systems to achieve recognition. Although such recognition between an association and a government entity is not prohibited, these government agencies are concerned about having to enter into agreements with a multitude of systems in the United States.

It is our impression, based on discussions in mid-April with representatives from the U.K. system and mid-May with personnel from the Italian system, that no new agreements will be made with systems outside of Europe, either government or nongovernment, until the European Organization for Testing and Certification (EOTC) establishes policy in this area.

In Other Countries. A2LA has successfully negotiated an agreement with the Government of Hong Kong through its Hong Kong Laboratory Accreditation System (HOKLAS). HOKLAS has a similar agreement with the United Kingdom government system and with the Australian Association which performs the vast majority of accreditations in that country. We have asked the Office of the U.S. Trade Representative and the Department of Commerce, using the Free Trade Agreement as a basis, to enquire into the lack of response we have received from our proposal to the Canadian accreditation system. We expect to sign an agreement with the Australian system this summer. There is more interest in cooperation from systems in other countries than there is from systems in the United States. But these international negotiations are expensive for a relatively small organization such as ours; we have not been able to make the contacts we would like in order to develop additional agreements with systems in other countries.

QUALITY SYSTEM REGISTRATION

A rapidly developing concept, quality system registration, is significantly affecting commerce between suppliers of materials and components in the United States and their customers in Europe. Under this concept, purchasers of finished goods rely on a third party to verify that the maker of such goods has in place a quality system meeting the requirements of an international standard (one of the ISO 9000 series of standards). All aspects of the design, production and distribution system can be assessed to these standards. In turn, manufacturers seeking registration are requesting that their suppliers also meet these standards, since all elements in production are to be properly controlled in a recognized quality system.

A2LA has been concerned about this development because of the role of testing in assuring the quality of the product. It seems to us that quality system registration and laboratory accreditation may end up being the dominant joint mechanism for attesting to the quality of products in the years ahead. With this in mind, we have been talking with the British Standards Institution about possible cooperation in providing a registration service in the United States. We discussed the need for U.S. based auditors, and we have assembled a list as a basis for continuing discussions. A meeting of our quality system registration steering committee is scheduled for the end of July to see if there are enough resources to warrant proceeding with the development of an association-based system.

In Europe, the organizations which perform these quality system registrations are predominately associations. A European Committee for Quality System Assessment and Certification (EQS) has been established to coordinate activities in the various member countries. In addition, many member countries have government related entities which accredit the registrars and certification systems, and these will likely have a strong influence on the operation of EQS.

PRODUCT CERTIFICATION

Product certification systems have typically marketed a listing service in which products meeting certain standards were listed under the name of the producer. To determine if the products meet the standards, the certifier tests the products. Some certifications are based on only one prototype model of the product, others are based on representative units of production, selected so that a high degree of probability exists that the tests reflect actual production. Other systems reflect testing of all units of production (not possible of course for tests which destroy the product). Finally, some systems test representative products in the market place to verify conformance to the applicable standards.

Interest is growing among U.S. government organizations for this kind of specific listing of products. The General Services Administration is developing its own certification program and many other agencies by law operate such systems.

In practice, the new developments in Europe have not tended to favor extensive expansion of these kinds of approaches, although until the EC directives are finalized, there is still considerable uncertainty as to what will be required.

A POSSIBLE MODEL

Eleven and one-half years ago, in December, 1978, thirty (30) representatives of government, industry, professional societies, standards writing groups, testing laboratories, and consumers created and publicly endorsed a U.S. National Policy on Standards. The Committee which created this policy, the National Standards Policy Advisory Committee (NSPAC), believed this national policy on standards would create an environment in which "The nation's public and private standards capability could be effectively, economically, and equitably used on behalf of the national interest." In fact, this policy caused changes in the government through the Office of Management and Budget (OMB -- Circular A-119) and in the private sector through the American National Standards Institute (ANSI -- revised its process for accrediting standards bodies).

While the NSPAC did not directly address laboratory accreditation or product certification, it did suggest that this model for developing a national policy could apply to testing, product certification and laboratory accreditation. We in A2LA believe that an AD HOC Committee similar to the NSPAC should be established and implemented in order to develop a national policy on laboratory accreditation, quality system registration, and product certification. The policy would serve as a guide to existing private sector and government organizations in modifying their systems to meet the needs of the country.

RESPONSE TO THE HEARING QUESTIONS

With these reflections as background, we address the hearing's questions as follows:

1. Impact of the lack of a U.S. focal point on trade. We see the development of EOTC and EQS as the European attempt to arrive at a focal point for testing, quality system registration and certification policy. The predominant regional standards body, CEN/CENELEC, plays a dominant role in both of these coordinating activities. In the absence of a U.S. focal point, each U.S. system will have to "go it alone". The larger entities with major resources they can bring to bear on the issue will find the going easier. But even now some of them are seeking "accreditation" from European organizations. This makes up for a lack of U.S. policy by effectively becoming part of the European policy. With the absence of coordination and a U.S. focal point, these larger U.S. systems may find it necessary to make many compromises and adjustments to their operations while smaller systems will not even be able to participate.

2. Type of organization needed. If one were to take the European experience as a model, the organization would have to be a delicate balance of all interests. The private sector would have a strong operational involvement.

EOTC and EQS represent two somewhat different approaches in their detail, resulting from somewhat different circumstances, but are effectively similar in likely affect on European policy. An organization developed in the United States needs to provide balance among all interested parties. It needs to be a coordinating body hosted by government, with private sector secretariat, and evenly balanced membership. A2LA believes that an Ad Hoc policy group, a National Accreditation, Quality Registration, and Product Certification Policy Advisory Committee (NAQCPAC) should be established to develop a National Conformance Assessment Policy.

3. Demands placed on U.S. entities due to mutual recognition and reciprocity. In the absence of a U.S. coordinating function, each U.S. system would have to negotiate its own terms. Each system, operating on its own, would have less clout in resisting demands of foreign counterparts. Because the U.S. market is more flexible, these demands are likely to attempt to maximize U. S. market availability to foreign manufacturers.

4. Best way to gain acceptance. Government involvement will be necessary to gain acceptance. If a National Conformance Assessment Policy is effective, then the roles of government and private sector organizations will be apparent and cooperation between government and the private sector based on these roles will bring acceptance with the EOTC and EQS.

5. Is a U.S. national mark necessary? The usefulness of a national mark will depend upon how effectively it is controlled so that consumers at all levels have confidence in it. It is not at all clear that the EC mark will be effective for the full scope of conformance options for which it is now envisioned. Coordinating committee endorsement such as is now used in the standards arena (e.g. ANSI/ASME Standard ...) might be quite adequate.

6. Best method of achieving U.S. consensus on conformity issues. The biggest problem we have at present in the United States is that no one has prepared the "white paper", the vision, the role model, or the policy which will serve to coalesce public opinion and to focus the considerable energy now being expended. The model could come from an organization established by the Congress. We recommend that the Congress consider authorizing and supporting with modest funds a distinguished panel to develop a National Conformance Assessment Policy. This policy would not only guide government and private sector organizations in making changes to their operations to meet practices suggested by the policy, but would also set up a framework whereby both government and private sector organizations meeting these practices can earn national recognition. Standards policy (resulting in OMB Circular A119 and changes to ANSI's administration as national standards coordinator) developed more than a decade ago could serve as a model.

John W Locke

American Association For Laboratory Accreditation

ATTACHMENT 1

JOHN W. LOCKE

President
American Association for Laboratory Accreditation (A2LA)
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John Locke has managed the Association, which is about 12 years old, for the past four years. Before that, he served as a consultant for a year in the field of occupational and environmental health and safety. His previous experience in laboratory accreditation was as coordinator of the National Voluntary Laboratory Accreditation Program (NVLAP) at the Department of Commerce from January 1978 until March 1982 and then as Manager of Laboratory Accreditation (and NVLAP) from March 1982 until March 1985 when the program was transferred to the National Bureau of Standards (NBS), now known as the National Institute for Standards and Technology (NIST). In this latter capacity, he received the 1984 Department of Commerce Bronze Medal for Superior Federal Service with the Citation:

> For outstanding contributions to national and international laboratory accreditation and leadership of the National Voluntary Laboratory Accreditation Program.

His association experience dates to the mid 1970's when he was Technical Director of the Can Manufacturers Institute. Before that he was in the technical consulting business with Booz Allen and in the aircraft design and manufacturing business with McDonnell Aircraft (now McDonnell Douglas)

Locke has been chairman of ASTM's Committee E-36 on Laboratory and Inspection Agency Evaluation and Accreditation for over four years and continue to serve in that capacity. He is a member of the American National Standards Institute (ANSI) Certification Committee, the ANSI International Certification Subcommittee, and the Department of Commerce/Office of the Trade Representative Industry Functional Advisory Committee on Standards for Trade Policy Matters (IFAC-2). He is a member of the American Society for Quality Control (ASQC) Technical Advisory Group on the International Standards Organization Technical Committee (TAG to ISO/TC 176) on Quality Assurance and actively participates in the International Laboratory Accreditation Conferences (ILAC).

Mr. Locke holds a B.S. in Aeronautical Engineering from the University of Illinois and is a Certified Safety Professional.

American Association For Laboratory Accreditation

FACT SHEET

The **AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION (A2LA)** is a nonprofit, nongovernmental, public service, membership society dedicated to the formal recognition of competent testing laboratories. Accreditation is available to any type of testing laboratory, be it private (independent or in-house) or government. Accreditation is based on internationally accepted criteria for competence for testing laboratories (ISO/IEC Guides 25 and 38).

Membership in **A2LA** is open to any individual, institution or corporation interested in the recognition of competent testing services. Members pay dues, attend meetings/symposia sponsored by the Association, and receive the Association's publications such as the periodic newsletter, A2LA News, and the A2LA Directory of Accredited Laboratories.

Goals. The goals of **A2LA** are to: (1) provide a comprehensive national laboratory accreditation system thereby improving testing within the United States and enhancing the quality and reputation of U.S. goods in markets at home and overseas; (2) provide publicity for accredited laboratories and a service to their users through the publication of an annual directory of accredited laboratories, newsletters, press releases, articles, and other related documents; (3) negotiate agreements on mutual recognition with other laboratory accreditation systems and thereby strive for national and international acceptance of the competence of accredited laboratories; and (4) eliminate unnecessary multiple assessments of laboratories.

Organization. **A2LA** is governed by a Board of Directors whose members represent the professions, industry, labor, laboratories, and government. The Executive Committee of the **A2LA** Board of Directors:

- Chester N. Grant, Chairman of the Board. General Motors
- Paul Schlecht, Vice Chairman. NIOSH
- John A. Blair, Secretary. Du Pont
- Kenneth A. Kun, Ph.D., Treasurer. Syracuse Research Corporation.
- Gladys B. Berchtold, Past Chairman. Standard Laboratories, Inc.
- Carl E. Miller, Chairman of the **A2LA** Criteria Council. Factory Mutual Research
- Earl Hess, Ph.D., Chairman of the **A2LA** Accreditation Council. Lancaster Laboratories, Inc.

Other members of the Board of Directors include:

- Ronald R. Christensen, Association of Official Analytical Chemists
- James S. Bigelow, Exxon Chemical, Polymers Group - Americas.
- Wallace D. Edsall, Allegheny Ludlum Steel
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Nancy Trahey, National Institute of Standards and Technology

Councils. The Board maintains two councils: (1) the **Criteria Council** which oversees the development and interpretation of criteria documents and (2) the **Accreditation Council** makes final recommendations for granting, denying, or terminating accreditation, based on the assessment and evaluation provided by the **A2LA** assessors and staff. Appeals of Council decisions are made first to the Council and then to the Board of Directors.

Staff. The President of the Association is John W. Locke. Other staff members are Peter S. Unger, Vice President, Roxanne Robinson, Scientific Officer, Lisa C. Drake, Staff Director, and Brandy Walker, Staff Assistant. A2LA has trained over 40 testing experts to conduct on-site assessments. Assessors are employed on an as-needed basis.

Accreditation has been granted in the Biological, Chemical, Construction Materials, Environmental, Geotechnical, Mechanical, Metrology, Nondestructive, and Thermal fields of testing. As of May 30, 1990, **A2LA** has accredited 222 laboratories in 34 states, Guam and Canada in the following fields:

Bio	Chem	CMT	Env	Geo	Mech	Metr	NDT	The
4	55	43	28	16	65	2	7	2

Over 53 additional applications are being processed. Users of laboratory services are advised to seek the specific scope of accreditation from any accredited laboratory. The scope identifies the tests or types of tests for which the laboratory is accredited. Accreditation has been granted for testing in some more specific areas including automotive, coal, and metals.

Recognition. Several organizations, including General Motors, the New York City Transit Authority, the City of Houston, the States of New Mexico and Kansas, and the U.S. Department of Defense recognize **A2LA** accredited laboratories. A metals program has been developed specifically for the Defense Industrial Supply Center to help eliminate the problem of counterfeit fasteners being introduced to the U.S. marketplace.

A2LA has established and maintains a Quality Manual and conforms to the ISO Guides 54 and 55, "Testing Laboratory Accreditation Systems -- General Recommendations for the Acceptance of Accreditation Bodies" and "Testing Laboratory Accreditation Systems -- General Recommendations for Operation."

Funding. **A2LA** is funded by dues from members, fees charged to laboratories seeking accreditation, training courses and seminars, and donations. Training is given in laboratory quality assurance, assessment, safety and environmental management. Most of **A2LA's** resources are used to monitor the performance of enrolled laboratories.

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Mr. **Valentine**. Thank you, Mr. Locke. Thank all of you.

I would like to, by way of summary, at least in part, ask this question of each one of you. If you could, beginning with Mr. Wilgis, if you could give us your judgment as to the major barriers which exist to the establishing of a focal point organization for testing and certification.

First of all, let me stop there. What barriers do you see to that?

Mr. **Wilgis**. Mr. Chairman, as we stated in our statement, we believe that it is very much recommended that we continue to have a system in the United States for testing and certification that involves both the private sector and the government. We have a wealth of experience and expertise in the private sector that we certainly do not want to disregard.

At the same time, we have to recognize that the private sector cannot do it by itself. We need the authority of the United States Government, particularly in the international arena, to negotiate with other organizations such as the European Community. Pulling this together is a difficult task. I see that as the task ahead of us.

Mr. **Valentine**. Is it a question of the Government regulating the regulators?

Mr. **Wilgis**. If you put it the question of the Government accrediting the accreditors, I would say that would be a role that the Government could very well play in this system.

Mr. **Valentine**. Mr. Bhatia?

Mr. **Bhatia**. Yes. Let's recognize, first of all, that we have well-established systems of safety networks, codes and services and jurisdictional parties. I was speaking to some industry people yesterday, some of whom are in this room, and the comments that we heard repeatedly from the industry groups and the code officials and the jurisdictional parties was that—given our present system of state and local enforcement of regulations and local codes, the laws that are involving these codes and regulations, enforcement, and parties such as IAI members, the inspectors, the health officials, the code officials, the NFPAs development of a focal point at a Federal level cannot and should not ignore those jurisdictional parties and their responsibilities and obligations.

Secondly, we need to assess what development of a focal point of this type will cover. Is it going to be information coordination; is it going to be dissemination of information; or is it actually going to involve accreditation? If it involves accreditation, there are existing functions which have been congressionally authorized, which reside in Federal agencies, and others which reside at various levels of governments, that are taken care of in many instances, quite adequately I may say, in the private sector. What will be the impact on that? And what will be the cost of making those shifts and what will be the U.S. industries' response to those changes, and how would it really help them? I think those are the issues that need to be looked at.

You talk about barriers. I present to you all of these.

Mr. **Valentine**. Mr. Frier?

Mr. **Frier**. Yes, sir. As far as barriers are concerned, if you would be a manufacturer in the United States and you had products that did not necessarily come under OSHA's jurisdiction, where they had the authority, or the states, you could possibly not be able to sell these in places like Oshkosh, WI or Kalamazoo, MI or any of these individual jurisdictions. Just because you couldn't sell them, you couldn't, as a manufacturer, offer the ability of your distributors to sell them anywhere at all. That, of course, is a barrier. If you didn't get them certified at one particular location, you couldn't have a carte blanche ability to distribute these products everywhere in the United States.

The Europeans, however, can provide you the ability to sell products anywhere within their jurisdiction if you comply with their rules. So I say barriers definitely exist in the United States for certain regulated products when they do not fall under OSHA's jurisdiction.

It just so happens that OSHA is the only agency that does have the ability to tell the local jurisdictions in certain areas, for certain items of equipment, that they must accept the products. But except for those items, if it's not under their jurisdiction, the barriers do exist and there is definitely a hindrance of manufacturers to have the free ability, whether it be in this country or in foreign countries, to sell their products freely anywhere in the United States. They cannot make that decision on their own.

Mr. VALENTINE. Mr. Locke?

Mr. LOCKE. I have a statement on page 2 of my statement—which I didn't read, but I would like to read it. It says, "It is likely that lack of confidence in another system's ability to address what is considered 'my area of expertise' is also at work." That is to say, I think we're all pointing fingers and saying well, I can't trust you and you can't trust me, and what you're doing isn't right and what I'm doing, and we don't really even know how the other system operates. And this is not only in the private sector. It's in spades in the government sector.

We saw the Customs Service, for instance, put in its own laboratory accreditation system for some narrow area of interest. The Agriculture Department has many laboratory accreditation systems. And there are various laboratory accreditation systems.

We had a conference in May and we tried to get these people to talk to each other at the conference. We had about 11 or 12 laboratory accreditation systems there. Everybody talked very deliberately and very fully about their system, but nobody was interested in talking to each other about what could be done about it.

The last point I would like to make is I think, since there isn't any policy, there isn't any overview, there's no vision, I think that's what's missing.

Mr. VALENTINE. Well, haven't you more or less put your finger on the part of the—maybe a large part—of the argument for the further insinuation or intrusion of the Federal Government into this area, because—with all its imperfections—because this is left to a loose, or maybe not so loose, voluntary arrangement. You know, there's always the suspicion, isn't there, that I'm doing it but I don't know whether my competitor is doing it. If the Government says you must do it, they might not catch everybody, but, you know, you do have the realization that if they catch your competitor, they bust his tail.

Is that—You know, what you said, is that really—What I said, is that really a reason, or a good enough reason for the Government to become more involved in it?

Mr. LOCKE. Well, I have a lot of problems with that, because the same problem I'm talking about in the private sector is going on in the Government. You got competition going on in the Government among systems. You even have two different laboratory accreditation systems headquartered at NIST. They're not dealing with each other, they're not working together. It's not just the private sector. It's the Government as well.

What I'm suggesting here is not a Government organization to manage this. What I'm suggesting is a modest policy developing concept, a committee, if you will, for a period of one, perhaps one-and-a-half years—this is what the NSPAC experience was—to create this vision that will demonstrate where everyone fits within this, and we'll talk about the marks and we'll talk about the international systems. We don't have the vision that is being agreed to and accepted.

Mr. VALENTINE. Thank you, sir. I'm just trying to figure out what all those lights up there mean, whether that's one of those strange quorum calls that we get over there. Thank you, sir.

Mr. Wilgis, can you give us an estimate of the amount of business that private laboratories in the United States would stand to lose if they are unable to receive this so-called "notified body" status, which I find an interesting expression, how much business they would lose if they can't receive that type of designation by the European Community?

Mr. WILGIS. Mr. Chairman, I cannot give you a figure on that today. We'd be glad to research that to the extent of our ability, if you would like—

Mr. VALENTINE. Well, it would be very helpful to us. I don't mean, you know, to make it into a major project, but if you get some kind of an estimate, that would be helpful.

Mr. WILGIS. I do know that our members that do test products for the European market would be very seriously affected by this action. I would suspect that, over the years, as certification becomes more important, and as the Common Market pulls together their system, it would be an increasingly serious problem, particularly in areas of laboratory services, such as environmental protection.

Mr. VALENTINE. Mr. Bhatia, I want to ask you some questions about the UL mark there. I have toured the part of your facility in the Research Triangle Park. It's a fascinating experience. At that facility you see people trying to capsize a boat in a pond and somebody else slamming television sets, dropping it off of a table to see how many feet it falls before it smashes to pieces and that sort of thing.

What do you think is the best way to achieve the status of a UL mark with products that are not covered by that mark? And do we need some sort, in your opinion, some kind of a US mark, and what would be the ideal?

Mr. BHATIA. Okay. Let me first clarify that the UL mark, as we know it, and even as it is accepted in other nations, signifies conformity to U.S. standards and to U.S. codes. So the acceptance and recognition of that mark really demonstrates compliance to the U.S. system. It is not accepted as a demonstration of compliance to the foreign national codes and foreign national standards.

Now, in order for us to talk about a U.S. national mark, we have to recognize that marks will be needed to identify compliance to various types of programs and various types of hazards and services. UL, for example, always needed an FCC mark to demonstrate conformity to FCC requirements. If you buy butter, you're going to look for that FDA mark. That's going to be needed. You'll need the electrical mark perhaps signified by UL. You may need the FN mark for fire properties. You may also need special marks for components, marks for demonstrating conformity to accreditation schemes. And one mark, quite practically, is not logically going to do that for you.

You also need to make some assessments as to what that mark stands for. Were all the elements covered; what was the competence of the entity which led you to the conclusion that allowed you to place that mark, is that even verified and checked? What is the marketplace acceptance of that mark?

We heard this morning from Mr. Deusterberg and from the other representative from DOC that even the EC mark itself is not going to gain you marketplace acceptance in Europe. It's going to be a passport to get you legally into the 12 nations, but the marketplace acceptance of even that mark—and that is legally mandated—is not going to be sufficient by itself. In many cases, the marks of certifying organizations, the entities that help you achieve the CE mark are going to be placed right next to the CE label.

So to discuss a national mark, I think, without recognizing those marketplace demands and needs and the forces that come into play relative to competence, relative to thoroughness, and relative to acceptance by parties, by public and by manufacturers, I think, is premature.

Mr. VALENTINE. Thank you, sir.

Mr. Frier, in your testimony you cite OSHA as the only governmental agency that has a statutory certification authority over all other jurisdictions with regard to requirements of the workplace. Can you amplify briefly the very special role that OSHA has with regard to workplace certification and what elements of their operation might be more generally applied to a national testing and certification system?

Mr. FRIER. Well, sir, most of the regulated products, you might say, would fall under OSHA's general authority when those products appear in the workplace. And according to Federal law, the workplace is any, I think, entity that has—employs over five people. So it generally includes most locations, with the exception of residences. So it's pretty general as far as what their authority is.

Their problem is, they do only have certain parts of the items that are covered by their standards. There are still many items that are not under their standards. Certain mechanical items are not under their standards. So it's only the things that they have identified in the electrical section S, subsection S, which is their electrical, that they have covered.

But it is the first step to have a laboratory accreditation program that mandates that jurisdictions must accept that certification as long as the jurisdiction is a State jurisdiction. OSHA does not have the jurisdiction over the local municipalities. If they choose not to accept it, they really don't have to. But it is something that provides a tremendous amount of credibility for laboratory accreditation when they know the State allows it, and generally the municipalities can fall in and start accepting it. But that is the first thing that existed in the United States that will allow the Z34 standard that I mentioned and other types of programs to assure that when a product contains a mark, that that is part of the OSHA regulation, that is part of what they're calling the nationally recognized testing laboratory program, that that jurisdiction probably will accept the mark.

Now, it is true that there is a marketplace demand that certain people will look for a particular certification agency or laboratory. But those kinds of confidences have to be developed, exactly like in the EC, in the European market. The CE mark is, true, is not nationally going to be acceptable by everyone. There are certain people that are going to have more competence in one laboratory over another. But the point is it is legally able to be sold and it's up to the laboratories or manufactures that use that in order to develop the—or produce the competence that the public has to have in order to accept the mark, knowing that the authority that's watching the laboratories and watching the certification and watching the application of the mark is doing its job and a product can be trusted and the services that the mark represents can also be trusted.

Mr. **Valentine**. Thank you.

I have other questions but we've got a quorum call and that'll be followed perhaps by other votes, so I'm not going to ask you to wait here. I will say again that we appreciate the time and effort which went into the preparation of your testimony and the time that you've spent with us has been very helpful.

The subcommittee will stand adjourned.

Mr. **Locke**. Thank you, Mr. Chairman.

[Whereupon, at 1:35 p.m., the subcommittee adjourned.]

APPENDIX

NEMA

National Electrical Manufacturers Association
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STATEMENT OF

THE NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

SUBMITTED BY

BERNARD H. FALK

PRESIDENT

TO THE

SUBCOMMITTEE ON SCIENCE, RESEARCH, AND TECHNOLOGY

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

U.S. HOUSE OF REPRESENTATIVES

FOR THE JUNE 26, 1990 HEARINGS ON

THE FEDERAL ROLE IN INTERNATIONAL

TESTING, CERTIFICATION AND QUALITY ASSURANCE

Statement of the
National Electrical Manufacturers Association

The National Electrical Manufacturers Association (NEMA) represents over 600 American electroindustry companies that manufacture products used in the generation, transmission, distribution, control, and end-use of electricity. Products include industrial automation equipment, lighting equipment, building equipment, insulating materials, wire and cable, power equipment, certain electronic products, and diagnostic imaging and therapy systems products. Our members serve a domestic market in excess of $70 billion and export about $10 billion worth of product. They employ over 500,000 Americans. NEMA membership consists of a mix of large, medium and small firms.

This statement presents NEMA's views on international and regional (e.g. European Community (EC) 1992) product testing, certification and quality assurance programs that impact, or may impact, U.S. electroindustry manufacturers. It also presents suggestions on how U.S. interests on these issues could be better represented in regional and international arenas. It should be noted that a NEMA statement was presented at the June 19, 1990 House Subcommittee on Science, Research and Technology Hearings on "The Federal Role in International Standards". Since the subjects of "standards" and "testing and certification" are closely related, both statements should be reviewed to obtain an overview of NEMA's views on these issues.

I. Current International Testing and Certification Programs

Only a few international programs for testing and certification presently exist. The International Electrotechnical Commission Quality Assessment System for Electronic Components (IECQ) provides a certification system by which electronic components made by approved manufacturers may be used confidently by buyers anywhere in the world without need for further testing. Manufacturers may obtain IECQ certification only after subjecting their production facilities to an examination by a third party inspectorate. The inspectorate determines that the manufacturer is capable of manufacturing and testing the device to IECQ standards. Currently 23 countries (including the U.S. via the United States National Committee to the International Electrotechnical Commission (USNC/IEC) Electronic Components Certification Board) participate in this program.

An international program for mutual recognition of test results as a basis for certification at the national level is also in operation. The IECEE (IEC System for Conformity Testing to Standards for Safety of Electrical Equipment) is a program to facilitate international trade in certain electrical products by simplifying product certification at the national level. This is achieved via reciprocal recognition of IEC safety standard tests results generated by testing laboratories in participating countries. The testing activities of the IECEE program, called the CB Scheme, involves establishing National Certification Bodies (NCBs) in participating IEC member countries throughout the world. NCBs are recognized to test products to one or more IEC safety standards. A manufacturer in a participating country can have his product tested at a designated NCB, and obtain a test certificate and test report indicating that the product has been tested and found to conform to relevant IEC standards. This test data can be presented as evidence to NCBs in another member countries where the manufacturer wants to obtain national certification. If no national deviations exist the manufacturer may receive national approval or a mark of conformity from NCBs in other member countries, subject to national provisions. Manufacturers in 25 countries worldwide have benefited from participation in the CB Scheme. To date the U.S. has not participated in the CB Scheme due to the lack of standards harmonization. Recently there has been considerable interest expressed by certain U.S. industries in U.S. participation in the CB Scheme of the IECEE program.

Firms concerned about EC 1992 and the related testing and certification programs should be especially interested in the IECEE Program. There are indications that agreements made via IECEE will continue to be recognized by the EC after 1992. This is especially important to firms with products covered by the EC Low-Voltage Directive such as many NEMA member companies.

The USNC/IEC is currently reviewing US participation in the IECEE Program and the CB Scheme. Public and private support for such programs can aid U.S. firms cope with the demands imposed by regional product testing and certification programs. It should be noted that the IEC is considering similar safety certification programs covering electromagnetic compatibility, equipment used in potentially explosive atmospheres, and software.

II. European Community (EC) 1992 Issues

The EC is working to harmonize European standards and product testing and certification requirements. Product testing and certification are areas where differing U.S. and European approaches have created uncertainty. For many products sold in the U.S., such as large, heavy electrical equipment, only manufacturer's self-certification is currently required. The manufacturer is responsible for ensuring that his product is safe, and meets the requirements of its intended application. While third-party testing and certification is available in the U.S., the primary responsibility for product safety and serviceability rests with the manufacturer. In Europe, third-party testing and certification programs, and laboratory accreditation schemes, are more extensively used. European customers tend to rely more on product testing and certification programs than do U.S. customers.

Given the dissimilar approaches to product certification and testing in the U.S. and Europe, the EC "Global Approach to Product Certification and Testing" has raised a number of questions. While the Global Approach methodology appears to describe a logical approach based upon European attitudes, will this approach limit U.S. access to European markets? Will the attainment of a "CE mark" become a barrier to trade, rather than a passport to the EC marketplace? Will U.S. firms currently doing business in Europe be able to continue business as usual after 1992?

The question of access to certification and testing services is an important issue, especially in the area of regulated products. Products that are required to be third-party tested to demonstrate compliance with the essential requirements of EC Directives before they can be marketed must have reasonable access to testing. It is not yet clear whether U.S. firms will have reasonable access to the European laboratories that provide EC testing. It is also not clear what role U.S. laboratories will be permitted to play in the process of EC testing. Will existing or new bi-lateral agreements for mutual recognition between U.S. laboratories and European laboratories be recognized or allowed after 1992? If so, will they cover part or all of the testing? In addition, if the EC provides U.S. manufacturers with open access to testing, what will the EC ask in return? Will our current free market concept be acceptable to the Europeans, or will they insist that the U.S. system be modified to parallel the proposed centralized European system under the auspices of the European Organization for Testing and Certification (EOTC)? Considerable study is required to evaluate whether the U.S. needs a focal point to parallel EOTC. Given our present system of state and local government enforcement of electrical installation practices and product approval, this may not be appropriate.

Another important area is product quality and quality system assessment, and their relationship to EC product certification programs. The "Global Approach" methodology relies heavily on the EN 29000 series of quality management standards (which are based on the ISO 9000 series). The EN 29000 approach provides basic inspection oriented standards, not the total quality system approach adopted by programs such as the U.S. Malcolm Baldridge National Quality Award. In high-tech areas that have adopted total quality system programs beyond the scope of EN 29000, acceptance of EN 29000 as a baseline program could result in a reduction in the acceptable level of product quality. It is also possible that the EC insistence on EN 29000 could even act as a non-tariff barrier to trade. Firms with more stringent programs than EN 29000 may not be willing to modify their quality programs to meet EC requirements. In addition, having a U.S. facility registered to EN 29000 may present the same difficulties as obtaining EC acceptable product testing.

III. U.S. Response to Regional Testing and Certification Programs

Meeting the challenge presented by regional testing and certification activities such as EC 1992 will require public and private sector cooperation. In regulated product areas, especially those that are regulated in both the U.S. and the EC, government to government negotiations may be required. The U.S. government should consult with private industry, before and during these negotiations, in order to provide private industry an opportunity to offer advice on the impact of proposed U.S. government positions. Similarly, in product areas where a product is regulated in one region but not regulated in the other, strong government/private sector cooperation should be established in order to develop appropriate U.S. responses. While it is desirable to gain access to EC markets, we must be careful that the health and strength of our current system is not unduly compromised. In this respect, we are pleased with the formation of the Department of Commerce Advisory Committee on the European Approach to Standards, Testing and Certification in 1992.

In non-regulated areas, the primary role of government should be to work to seek and promote equivalent competitive access to foreign markets for U.S. firms. By working through existing programs, such as those sponsored by the Office of the U.S. Trade Representative, and existing agreements, such as the GATT Treaty, the U.S. government can provide U.S. manufacturers that wish to market abroad an opportunity to do so. It is NEMA's opinion that government involvement beyond ensuring that U.S. manufacturers have fair access to foreign markets would be overstepping the current authority vested in the Federal Government. Legislation and funding to authorize and support expanded government involvement in international and regional testing and certification activities would be required, and we see no justification for any such actions.

The current U.S. system of self-certification has served U.S. industry well to date. In light of increased international and regional demands, it may be worthwhile to evaluate closely how well the current system can react to increasing internal and external demands. Joint private/public efforts in this evaluation process would be beneficial.

IV. Recommendations

There may be some elements in our current voluntary system which could be improved. If this hearing identifies specific problems in the areas of product testing, certification and quality assurance programs, consideration should be given to conducting a detailed study to investigate possible improvements in our current system, and to review ways to achieve a more cooperative relationship between the private sector and U.S. Government. The study should be conducted under the auspices of the American National Standards Institute (ANSI), and the study panel should include key industry executives along with representatives from both the legislative and executive branches of the U.S. government. The study panel should review present testing and certification needs, evaluate current programs designed to meet these needs, and if necessary recommend changes needed to ensure that U.S. firms will have reasonable access to global markets.

With respect to EC 1992, given fair treatment, American manufacturers feel that they can continue to successfully market products in Europe. The thrust of any future action related to regional activities should be to ensure fair, non-discriminatory treatment for U.S. firms. The Federal Government should play its part in ensuring that EC and other regional markets do not discriminate against U.S. made products. Care must be taken to ensure that in the process of gaining access to international markets, the viability of our current free market system is not compromised.

Finally, additional attention should be given to international activities designed to ease the burden of national and regional testing and certification programs. The IECQ and IECEE programs are examples of such programs. Public and private support for, and participation in, these types of activities will help keep global markets open to all parties.

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JUL 2 1990

July 17, 1990

The Honorable Tim Valentine
Chairman
Subcommittee on Science, Research
and Technology
Committee on Science, Space and
Technology
Rayburn House Office Building -
Suite 2321
Washington, D.C. 20515

Re: Hearing on the Federal Role in
International Testing, Certification
and Quality Assurance

Dear Congressman Valentine:

I am the Vice President, Washington Office, of the American National Standards Institute, Inc. (the "Institute"). As you know, the Institute is the coordinator of the U.S. voluntary standards system and serves as the U.S. member body to the International Organization for Standards ("ISO") and, through the U.S. National Committee, the International Electrotechnical Committee ("IEC") -- the leading, non-treaty international standards organizations. In connection with this aspect of the Institute's activities, I was pleased to appear before the Subcommittee on June 19, 1990 during its hearing on the Federal Role in International Standards.

At that time, you mentioned the Subcommittee's upcoming hearing on the Federal Role in International Testing, Certification and Quality Assurance, and we made it a point to attend that session on June 26, 1990. Based on the oral and written testimony provided at the hearing, the Institute felt it important to apprise you and the other Members of the Subcommittee of the views of the Institute in this area as well.

Accordingly, this letter is written for that purpose, and the Institute requests that the letter and enclosures be included in the hearing record.

* * *

While the Institute is certainly best known for its important work in the standards field, the Institute is also very much involved in certification, testing and other allied activities. This has been particularly true during the last several years when the interest of the Institute's members in these areas has increased significantly.

The Institute's Constitution specifies that, among other things, it shall:

- serve as the national coordinating institution for voluntary certification programs;
- provide the means for determining the need for new certification programs;
- establish, promulgate and administer procedures and criteria for recognition and accreditation of certification programs;
- represent the interests of the United States in international nontreaty certification organizations; and
- serve as the clearinghouse for information on certification and related activities in the United States and abroad.

In addition to accrediting several certification programs, the Institute has approved as American National Standards two important documents concerning certification: American National Standard Z34.1 (Third Party Testing Programs) and American National Standard Z34.2 (Self-Certification by a Producer or Supplier). Both of these standards have been widely adopted by government agencies and the private sector.

Within the Institute, the Certification Committee is responsible for administering all its certification activities. A subcommittee of the Certification Committee holds the U.S. TAG for participation in the joint ISO/IEC Certification TC known as CASCO. The Institute is an active member of CASCO, as demonstrated by the fact that, thus far, the ISO/IEC guidelines for certification have been substantially based on the Z34 Series of American National Standards. In turn, the ISO/IEC guidelines for certification have been widely adopted -- for example, in Europe by the Committee European Normalization (CEN) and the Committee European Normalization Electrotechnical (CENELEC) as the EN 45000 Series.

As with all of its activities, the Institute seeks to be responsive in testing and certification to the needs of its members in a changing, increasingly global, marketplace. To that end, the Institute's Board of Directors has established a special study group whose mission includes making recommendations to the Board about future Institute initiatives in these fields. That group has been particularly active in recent months given the process occurring in Europe as part of EC-1992. The initial recommendations of the study group, which were presented to the Institute's full Board in March and now are being further refined, are:

1. There needs to be a cooperative relationship between the private sector and U.S. government (legislative and executive branches) in dealing with EC '92 testing and certification issues;

2. The Institute should serve as a catalyst to bring together a broad coalition of private sector interests;

3a. The goal (insofar as testing and certification) is to achieve equivalent and competitive market access recognizing the role of testing and certification entities;

3b. The goal is for U.S.-made products to have access to both U.S. and European markets without being exposed to duplicate testing and quality assurance activities;

4. The Institute should continue to serve as a resource in the U.S. for information about European testing and certification activities associated with EC 1992;

5. A key issue/objective is to assure that notified bodies accept data and test results from "qualified" bodies outside the E.C.

Since much of the testimony at the Subcommittee hearing focused on EC-1992, I would like briefly to offer the Institute's perspective on the unfolding events and to describe the Institute's role in the process thus far. One of the foremost priorities of the Institute has been to advance the interests of the United States in Europe not just with respect to standards, but also on emerging testing and certification issues. Last year, representatives of the ANSI federation first formally met with their private sector counterparts at CEN and CENELEC, including the individuals who have been charged with the task of creating the European Organization for Testing and Certification ("EOTC"). Testing and certification were important agenda items at the inaugural sessions.

In March of this year, during a further round of meetings between representatives of the ANSI federation and CEN/CENELEC, testing and certification issues were the primary focus (due, in part, to the considerable progress already achieved in the standards area). A comprehensive report summarizing these meetings (and otherwise identifying the evolving European positions with regard to testing and certification) was thereafter issued by the Institute's Brussels office. A copy of the report (the third in a continuing series) is attached for the Subcommittee's information.

Additional meetings with representatives of EOTC are scheduled for October 1 and 2, 1990. In recognition of the need for better coordination between the U.S. private and public sectors, the Institute has invited participation at these meetings by representatives of the Department of Commerce.

Based on the Institute's meetings and communications with the Europeans to date, it appears that there exists a true desire to create and implement a system in which a range of options will be available to U.S. and other manufacturers for the purpose of demonstrating conformity with product standards. The range of options for any particular product category will be defined based upon some criteria of risk but manufacturers themselves will also have some flexibility within the established range to choose an approach for demonstrating conformity with the applicable standards and requirements.

It will obviously be very important that U.S. manufacturers be permitted to select a means for showing conformity that will not place them at a competitive disadvantage to European or other suppliers in getting products to the market. While the Europeans have consistently maintained that they will treat imported products the same as products produced within the Community, many U.S. manufacturers prefer to be able to use self declaration of conformity or use local U.S. testing and certification agencies for independent third party evaluation rather than be required to use European entities. To the extent that self declaration of conformity will be accepted in conjunction with manufactured products in Europe, it will also be used by manufacturers elsewhere. This would presumably include the ability to use testing agencies outside of the EC to support a self declaration of conformity.

With respect to the role of non-European third party testing and certification organizations, the Europeans have maintained that to recognize a non-European entity as capable of evaluating conformity with the European requirements would provide an unfair advantage to non-EC based suppliers unless similar access to their national markets can be provided (i.e., Quid Pro Quo). Accordingly, it has been contended by some that when negotiating agreements to recognize non-EC based entities for conformity assessment, consideration should also be given to that entity's potential to offer a certification that will provide access to its national market for European manufacturers. This position is understandable but problematic because any such negotiations, if required, are certain to be both lengthy and arduous. Such a European posture would also appear to conflict in principle with several federal accreditation schemes in the United States where foreign laboratory organizations may be credentialed on the basis of their competence alone. It is not far in concept, however, from the National Recognized Testing Laboratory program of the Occupational Safety and Health Administration, which is of course bound to consider advice from the United States Trade Representative on applications from laboratories outside the U.S.

In recent months, the Europeans have evidenced a willingness to pursue simpler solutions and we should continue to urge that they do so. For example, European entities apparently will be allowed (perhaps even encouraged) to subcontract portions of their work to other entities so long as they do not thereby delegate ultimate legal responsibility. In this manner, private sector entities in the United States may conclude business arrangements based on data package exchanges with European notified bodies and thereby perform aspects of the conformity assessment work. A marketplace system might evolve among European notified bodies where the ability to have work performed in the United States by a U.S. entity could become the basis of operation between the U.S. and the EC. This solution should obviously be encouraged and promoted, since it appears to provide a means for a U.S. manufacturer to demonstrate its compliance with the European requirements through a U.S. entity that has negotiated a business arrangement with a European entity.

In assessing the overall situation relating to testing and certification in Europe, the Institute believes it is essential that the U.S. maintain flexibility and refrain from creating new structures (particularly governmental structures) that may not prove either necessary or desirable as events develop. The Europeans have expressed a strong desire to use existing private sector organizations as a principal means of interfacing on standards, certification and testing issues. Similarly, there should be an awareness that U.S. concerns are likely to vary considerably by industry and that any "solution," whether sectorial or more generic, must reflect and satisfy (to the extent possible) the views and interests of all materially interested parties.

In these circumstances, therefore, assuring a meaningful exchange of information and proper coordination become particularly important functions, and the Institute has devoted considerable effort to these challenges. By way of example, the Institute recently co-sponsored with the U.S. Chamber of Commerce a highly productive workshop on testing and certification. This forum provided an opportunity for experts in various industry sectors to share experiences in relating to European testing and certification organizations, and it was an important source of information for interested U.S. parties. One of the specific recommendations made during the workshop was that the Institute develop a formal means of interfacing with EOTC when that organization becomes operational.

Further, since it is believed that quality systems will ultimately come to assume an important role in both regulated and non-regulated industrial sectors, the Institute has organized a group to meet informally with representatives from the European Quality Systems Committee to discuss quality systems issues. Once again, in seeking to further meaningful private sector/public sector cooperation, the Institute has invited U.S. government participation at the meeting, which is scheduled for early August.

* * *

As shown by these and other activities, the Institute is committed to playing an active role in testing and certification consistent with the needs and wishes of its membership. We appreciate the opportunity to provide this information to the Subcommittee for inclusion in the record, and we would be happy to answer any questions you may have now or in the future.

Sincerely yours,

George T. Willingmyre, P.E.
Vice President

cc: J. Pearse
M. Peralta
B. Falk

SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY
OF THE
HOUSE COMMITTEE ON SCIENCE, SPACE AND TECHNOLOGY

WRITTEN SUBMISSION
OF THE
NATIONAL FIRE PROTECTION ASSOCIATION
CONCERNING
THE FEDERAL ROLE IN INTERNATIONAL TESTING, CERTIFICATION AND QUALITY ASSURANCE

RESPECTFULLY SUBMITTED,

NATIONAL FIRE PROTECTION
ASSOCIATION
BATTERYMARCH PARK
QUINCY, MASSACHUSETTS

DATED: JULY 20, 1990

EXECUTIVE SUMMARY

Developments in international markets, particularly the European Community's ("EC") imminent integration into a single market in 1992, have demonstrated the clear need for increased coordination of testing and certification in the U.S. Less clear is the organizational format -- public, private, or some combination of those -- by which the coordination will occur. Whatever the format, the consensus is that it should remain privately based and directed.

It is critical in this important area of public safety and international commerce that reasoned planning based, above all, on all available information, precede change. Thus it is crucial to receive input from all affected industries. The predominant role for the U.S. government (in particular the U.S. Trade Representative) should be to urge the equal and competitive access for U.S. firms to E.C. testing and certification programs, and to seek to impact European developments and procedures relating to the U.S. and third countries.

In the end, any changes should be no mere reaction to international events. The U.S. remains the largest market, and as such, has significant leverage in its own right. Moreover, the issues of public safety that are the fundamental premise for standards development are obviously inexplicably intertwined with certification and testing issues. Alterations to the testing, certification, and accreditation system that compromise that safety cannot be allowed.

I. INTRODUCTION

The Subcommittee on Science, Research and Technology of the House Committee on Science, Space and Technology held hearings on June 19 and 26, 1990, to receive testimony concerning the "Federal Role in International Standards, Certification, and Testing." The June 19 hearing focussed on standards development, while the June 26 hearing concerned certification, testing, and accreditation.

The National Fire Protection Association ("NFPA"), one of the largest U.S. standards developers, is greatly interested in both matters. NFPA has accordingly prepared an overview of its position on these issues for separate submission to the Subcommittee.

Hearings were held on essentially the same issues in early April, 1990 by the Department of Commerce's National Institute of Standards and Technology ("NIST"). Those hearings were intended to allow discussion of NIST's proposal to establish a Standards Council of the U.S.A. ("SCUSA"). As proposed by NIST, the SCUSA was to have oversight authority over all standards development in the U.S.; it was also to be the official U.S. point of contact for international standards development. NFPA joined many others in submitting written and oral testimony to NIST. In the end, opposition to the SCUSA proposal was voiced by the overwhelming majority of participants, including NFPA.

The Subcommittee convened its hearings for the stated reason that, while the NIST hearings discussed many facets of the international standards and testing/certification process, the participants arrived at little consensus as to a proper government role in this arena. The testimony received by the Subcommittee demonstrates that, in some measure, that lack of consensus has continued. Much of the testimony given to the Subcommittee closely mirrors that received by NIST during the April hearings. That is, there was opposition to any excessive government involvement into either the arena of standards development _or_ testing/certification.

As noted above, NFPA has elsewhere submitted its comments concerning the issues raised during the June 19 hearing on standards development. Because of the importance of testing and certification as mechanisms in the final _implementation_ of standards, however, NFPA also has a fundamental interest in the methods proposed to either revamp or oversee the testing and certification industry.

Moreover, to the extent that government regulation is proposed for one industry, it necessarily affects the other. Under Secretary of Commerce Robert White spoke accurately on June 19 when, in opposing material change in the Government's role in standards development, he stated:

> [I] believe in the value of a voluntary industry-led consensus system. Those who have lived with Federal regulation in other contexts have some basis to fear the camel's nose under the tent.

Oral Statement of Robert White, Under Secretary of Commerce, June 19, 1990 (Transcript p. 10).

As one of the most active standards developers in the United States, one active as well in international standards development, NFPA supports ongoing efforts to make the current system work better. In the standards area, this is best accomplished by continuing to support the activities of the American National Standards Institute ("ANSI"). In the testing/certification area, it is best accomplished by preserving the strengths of the diverse, decentralized U.S. system. Any increased coherence or direction that the system needs should be provided within that existing, private sector framework.

II. ANSI'S ROLE IN CERTIFICATION AND TESTING MUST BE RECOGNIZED

Overlooked by many of the submitters was the role that ANSI is already playing in this area. This is somewhat surprising, given that ANSI's Constitution lists that ANSI should, among other things, serve as the national coordinating institution for voluntary certification programs, and serve as an information clearinghouse for certification and related activities in the U.S. and internationally.

As mentioned by Mr. Leonard Frier, ANSI is already involved with an important aspect of certification through its Z34 programs, which include widely adopted standards relating to testing and self-certification. Most significantly, ANSI is proceeding to further develop a comprehensive approach to the issues involved with certification, testing, and accreditation -- domestically and internationally.

For example, meetings have been held between representatives of ANSI and the private European certification institute, EOTC. More are scheduled. A recent workshop on testing and certification sponsored by ANSI in conjunction with the U.S. Chamber of Commerce also specifically addressed the questions of concern to this Subcommittee. ANSI thus appears to be acting as a vehicle for coordination. Further recognition and strengthening of this role would require no great change in perspective by government or industry.

III. INCREASED COORDINATION OF TESTING AND CERTIFICATION, IF ANY, SHOULD REMAIN PRIVATELY BASED AND DIRECTED

The concerns of the National Fire Protection Association concerning testing and certification revolve both around the substance of the issues raised and the disturbing precedent that would be set by governmental oversight.

NFPA has reviewed the written and oral submissions by each submitter in the June 26, 1990 hearing.[1] The consensus of those submitting information was that the "diverse and decentralized" American system of testing and certification had worked well. The question presented, however, was whether the changes in the international trading environment -- particularly caused by the European Community's integration in 1992 -- might force changes on the U.S. in the form of a reordered system of testing and certification. The further question was what form the reordered system might take, and whether the government should act as a mere participant or as overseer. Under several proposals, the government would also act as the "focal point" for dealing with the European Community testing and certification issues.

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[1] Statements reviewed included those of the Honorable Norman Sisisky; Thomas J. Duesterberg, Assistant Secretary for International Economic Policy, U.S. Department of Commerce; Raymond J. Kammer, Deputy Director, National Institute of Standards and Technology; Herbert E. Wilgis, American Counsel of Independent Laboratories; Leonard Frier, President of MET Electrical Testing Company and Chairman of the American National Standards Institute's Z34 Committee; Joe Bhatia, Vice President, Governmental Affairs, Underwriters Laboratories, Inc.; and John W. Locke, President, American Association for Laboratory Accreditation.

To the extent that international developments require a response by U.S. standards developers and certifiers, ample provisions exist to allow for meaningful action. For example, although the European Community has said that the accreditation of the U.S. labs and certification bodies will only be permitted on the basis of formal "mutual recognition" agreements, the EC Commission has not demanded that mutual recognition agreements always be on a government-to-government basis. The Commission is prepared to negotiate agreements with both public and private sector testing and certification bodies outside the European Community. Therefore, even to the extent that agreements need to be consummated, agreements could be reached through private entities negotiating with their counterparts in the European Community or through negotiation by a U.S. umbrella organization based and directed in the private sector.

That extensive change should not be engaged in for its own sake was recognized by Assistant Secretary Duesterberg in his oral testimony. In response to a question from Chairman Valentine seeking Mr. Duesterberg's comments that both U.S. and European interests deserve more "coherence and uniformity in the U.S. regulatory system", Mr. Duesterberg stated that he:

> [did not] want to overdramatize this point. The one thing I would emphasis in this whole discussion is that, even though the U.S. system is diverse and somewhat decentralized, it has stood the test of time, and it has worked, and it provides a service to the manufacturing community and to the consumer that has worked well. . . I don't think we are going to be able to impose a system from above on the United States, or it is not going to gain acceptance from the manufacturing community...

Oral Statement of Thomas G. Duesterberg, Assistant Secretary for International Economic Policy, U.S. Department of Commerce, June 26, 1990 (Transcript p. 24-25)(emphasis added).

Mr. Duesterberg and NIST Deputy Director Raymond Kammer each noted the valuable information that would be gained by having industry-by-industry meetings to assess each separate industry's position on the need for possible changes in testing and certification. Such an effort would be valuable in formulating a strong and cohesive U.S. negotiating position, felt Mr. Kammer. Written Statement of Raymond G. Kammer, Deputy Director, National Institute of Standards and Technology, June 26, 1990 (p.6).

Deputy Director Kammer also noted the value of the present system. He declared that, even where there is a role for government-to-government agreement and negotiation, a combination of government or private organizations might be valuable:

> [W]e already have a lot of very successful and effective elements of certification system in the United States. The ASME [American Society of Mechanical Engineers] . . . have the boiler and pressure vessel code which is accepted all over the world. And UL, of course, their product testing is accepted internationally, too. One would want to be very cautious not to detract from the parts of the system that work exceptionally well already.

Oral Statement of Raymond G. Kammer, Deputy Director, NIST, June

26, 1990 (Transcript pp. 26-27)(emphasis added).

To the extent that the various affected sectors of the American economy have run into complexities in the American testing and certification industry, those matters should be addressed. Such information could be made available, as suggested by the Department of Commerce and NIST, through industry-by-industry hearings.

Assistant Secretary Duesterberg indicated, in fact, that the Department of Commerce was engaged in just this activity. In those discussions, "equal and competitive" access to testing and certification programs within the European Community for U.S. manufacturers must be a goal. As a means of promoting equal and competitive access, bilateral agreements, subcontracting arrangements, and memoranda of understanding should be developed to benefit both sides of the trading equation.

NFPA opposes the chartering of a Congressional Commission at this time to investigate these matters. Instead, the Congress should encourage the U.S. Government to work with the private sector through ANSI and various trade associations to find solutions to these complex issues. The recent workshop sponsored by ANSI and the U.S. Chamber of Commerce is a good example of how this should be done.

To the extent that further coordination of testing and certification is justified, NFPA joins with the other representatives testifying before the Subcommittee in recommending that any such coordination involve a high degree of private sector involvement. Some have testified that oversight by the government might be useful, even with private sector involvement. NFPA's position is to the contrary: any increased coordination of testing and certification should be privately based and directed. ANSI's role in the standards industry should be instructive here.

Using ANSI will enable the U.S. to maintain the benefits of the present private system while also not setting any unnecessary precedents for governmental oversight in other areas. In fact, the very success of the private system for the last fifty years argues for only the most rationally based and incremental change.

IV. Conclusion

The need for increased coherence and direction for the testing industry, especially in its international applications, can best be assessed after a thorough on-going analysis of information gained by an industry-by-industry review of actual problems faced, and the on-going participation of ANSI.

In the meantime, the Department of Commerce can, and should, continue its role as advocate for equal and open access for domestic certification and testing laboratories in their relations with all foreign countries.

Statement
# of the
AMERICAN GAS ASSOCIATION

Concerning

THE U.S. GOVERNMENT'S ROLE IN DOMESTIC AND INTERNATIONAL ACTIVITIES RELATED TO STANDARDS DEVELOPMENT, PRODUCT TESTING, CERTIFICATION, AND MANUFACTURERS' QUALITY ASSURANCE PROGRAMS

Presented by

Richard J. Schulte
Vice President, Laboratories
American Gas Association

Before the

National Institute of Standards and Technology
Hearings on Improving U.S. Participation in International
Standards Activities

U.S. Department of Commerce
March 22, 1990

I. INTRODUCTION

Mr. Chairman, members of the panel, my name is Richard J. Schulte. I am vice president, laboratories, for the American Gas Association (A.G.A. or the Association). I appreciate this opportunity to comment on behalf of A.G.A. concerning the U.S. government's role in standards development, product testing, certification and quality assurance. My testimony and comments are in response to the Notice of Hearing published in the Federal Register, November 29, 1989. (54 Fed. Reg. 48795). My presentation will consist of oral remarks supplemented by a written document for the record. The document filed March 22, 1990, contains both.

The American Gas Association is a trade association consisting of approximately 250 gas utility and pipeline companies who transport, distribute and sell over 80% of the natural gas used in the United States. The Association has its headquarters in Arlington, Virginia.

For 65 years the Association has operated A.G.A. Laboratories with facilities in Cleveland, Ohio and Los Angeles, California. The Laboratories is the principal U.S. safety certification agency for gas appliances and related equipment used in residential and commercial applications throughout the U.S. A.G.A. Laboratories is the administrative secretariat for approximately 23 committees and subcommittees that maintain 60 design standards and the National Fuel Gas Code for gas-fired appliances and accessory equipment. We are also one of the first U.S. organizations offering to audit and register manufacturers' quality assurance programs that comply with international standard ISO 9000. From this introduction, you can see that virtually all of the topics raised in your Notice of Hearing are part of our day-to-day domestic business.

We are also engaged in international activity. About 15% of our certification customers are located in foreign countries. The gas appliance sector that we serve is one of those subject to the "new approach" directives of the European Economic Community. We have a family of bilateral agreements installed or under negotiation with counterpart agencies in Canada, Europe and Asia; consequently, we are interested and involved in foreign trade matters.

From this national and international vantage point, I appear here to make four (4) general statements concerning the role of the U.S. government in standards, testing, certification and quality assurance matters affecting the gas industry. For purposes of this hearing, I use the term "gas industry" to include consumers, local code officials, gas pipelines and utilities and equipment manufacturers.

II. THE ASSOCIATION'S POSITION IN SUMMARY

First, the U.S. gas industry uses private sector systems for developing standards, writing model installation codes, certifying gas-fired equipment, and monitoring manufacturers' quality assurance programs. These systems are highly developed and widely accepted in our domestic market. The same systems are evolving through appropriate steps to satisfy new requirements in international markets. A.G.A. believes that the gas industry's private sector approach to standards development, product certification and quality assurance will continue to be more than adequate to serve future U.S. interests at home and abroad. Thus, we do not believe that our systems need to be augmented by creation of a new quasi-governmental accreditation body or adoption of new federal regulations. The gas industry is one area where business and local government have already demonstrated competence and foresight in protecting the consumer while constraining costs in a competitive environment.

Second, A.G.A. is convinced that both the U.S. government and private sector organizations (ANSI, other professional and trade associations, manufacturers and laboratories) have a shared responsibility for the success of U.S. trade with other nations. We believe the U.S. government and the private sector have complementary roles that require cooperation and communication across a broad front. We look for the U.S. Trade Representative, the Department of Commerce and the State Department to (a) conduct government-to-government negotiations where non tariff trade barriers impede the marketing of U.S.-made products abroad; and, (b) provide timely communications to U.S. industry as to the status and impact of such negotiations.

At the same time, A.G.A. expects the U.S. government to show restraint in a supportive role while private sector interests work out international arrangements for harmonizing standards, testing products and evaluating manufacturers' quality systems.

A.G.A. is an advocate for a partnership or alliance between government and private bodies. This alliance should operate to create an international environment wherein each U.S. industrial sector (steel, gas, medical equipment, information technology, automotive, and so forth) can work with its foreign counterparts to develop and use standards, test methods and certification procedures appropriate to that industry. The alliance of U.S. government and private interests should seek to operate by use of existing organizations without creating new agencies and imposing new administrative burdens and costs on business or the federal treasury.

Consistent with this philosophy, A.G.A. has endorsed formation of the Department of Commerce Federal Advisory Committee on the European Community Common Approach to Standards, Testing and Certification in 1992. Our endorsement is based on the expectation and belief that both U.S. government and private sector interests will make creative use of this Committee to develop an effective and well reasoned U.S. response to European initiatives.

Third, A.G.A. Laboratories has agreements in place for exchanging certification services with counterpart agencies in Europe. The EC Commission may require renegotiation of these agreements with U.S. government participation. A.G.A. looks forward to receiving assistance from U.S. government agencies if such negotiations are required; however, if EC approval of our agreements should require imposition of additional accreditation requirements, regulation and expense on the U.S. gas industry, A.G.A. will look upon these costs as a negotiating failure. We believe that the European and U.S. systems for standards development, testing, product certification and quality assurance can be different, and yet co-exist and interact successfully without being forced into a common mold.

Fourth, we encourage the U.S. government, and the U.S. Department of Commerce in particular, to become a constructive participant in U.S. private sector forums that are already available to receive, debate, find consensus and act on proposals for improving U.S. standards, testing, certification and quality assurance programs. I serve as a director of the American National

Standards Institute (ANSI), as does the Director of the National Institute of Standards and Technology (NIST). A.G.A. stands ready to receive from NIST a description of those real or perceived obstacles to trade that the Department of Commerce and the ANSI federation could address together.

These summary remarks comprise the oral testimony from A.G.A. The remainder of our written comments are submitted for the record.

They show, by way of example, the substantial progress being made by the American Gas Association, its customers and foreign partners to position the U.S. gas industry for future business success at home and abroad. These activities of the gas industry have not yet required U.S. government intervention, mandate or direction to be successful.

Thank you for this opportunity to speak on behalf of the American Gas Association.

AMERICAN GAS ASSOCIATION

SUPPLEMENTAL INFORMATION FOR THE RECORD

III. STANDARDS - NATIONAL

In the U.S. national or domestic market A.G.A. operates a key secretariat, supporting development and maintenance of product design and installation standards for gas-fired equipment and accessories. This secretariat serves three (3) accredited national standards committees, approximately 20 technical subcommittees, and numerous working groups and task forces. This family of committees involves about 300 participants from 200 U.S. organizations, including government agencies, manufacturers, utilities, testing laboratories, and consumer interest groups. This structure has operated successfully as a voluntary system for 65 years. It is accredited by the American National Standards Institute (ANSI).

A.G.A. spends almost $1.0 million annually in operating the secretariat for national committees Z21, Z83, and Z223. The organizations and individuals who participate in the structure probably invest 2 to 3 times this amount in the form of staff time travel and experimental work donated to keep the standards current and effective. We are not aware of any deficiencies in the domestic activities of this voluntary standards system that would be ameliorated by creation of a federal governmental alternative or accreditation program.

IV. STANDARDS - INTERNATIONAL

Participants in the U.S. gas industry's standards program are very much aware of the global markets developing for virtually all manufactured products. As of 1990, however, the major U.S. trading partner in gas appliances and accessory equipment is Canada.

For more than two years, the Gas Appliance Manufacturers Association (GAMA), A.G.A., the Canadian Gas Association (CGA), and standards committees in both countries have been working to achieve harmonization of U.S. and Canadian standards for gas-using equipment. We have targeted standards for furnaces, water heaters, boilers, ranges and decorative appliances for early conversion into a common North American format. Additional work is underway to harmonize U.S. and Canadian standards for fuel cylinders, refueling stations, and other facilities needed to support wider use of compressed natural gas as a transportation fuel. All of this activity is being undertaken because it makes good business sense, not because of government mandates. Gas utilities and appliance manufacturers are underwriting the cost of this work without placing new demands on constrained federal resources.

We do not believe that the gas industry's efforts to harmonize standards with Canada, or other nations, would proceed faster or with more credibility if additional government oversight or intervention were imposed on the industry's international standards activities.

V. PRODUCT TESTING AND CERTIFICATION - NATIONAL

A.G.A. has operated a national, voluntary product testing and certification program for 65 years. We estimate there are more than 150 million gas appliances in-service at this hour bearing the A.G.A. Blue Star certification seal. We provide certification services to product manufacturers located throughout the U.S. and in Europe, South America, China, Japan, Korea, Canada, Australia, and the Middle East.

The A.G.A. product certification program is formally accredited by the Occupational Health and Safety Administration (OSHA), administrative authorities in the states of Oregon and Washington, and city officials in Los Angeles and New York City. Even more important, our certification service and mark are accredited hundreds of times each day when consumers buy an A.G.A. certified product, code officials reference the A.G.A. Directory of Certified Products to approve an appliance installation, and manufacturers bring new appliances to the doors of our laboratories for testing.

To date, A.G.A. Laboratories has not sought a formal federal governmental accreditation of our testing and certification program. Said simply, we have not been able to identify a need for or the value of such an accreditation.

Moreover, we are concerned that any federal governmental accreditation program, operated to avoid restraints on domestic trade, will necessarily embody evaluation criteria commensurate with the lowest common denominator in laboratory practices. Given competition for certification assignments, testing agencies might be driven toward use of minimum test requirements and abbreviated procedures if this approach were adopted. A less effective consumer safety system could be the result.

A.G.A. is not an advocate for a national accreditation scheme, public _or_ private, for third party certification systems. At the same time, we are not opposed to continued study of and even participation in a national accreditation system _if_ a need for the investment develops, and a plan for adoption and enforcement of really meaningful accreditation criteria is promulgated.

VI. PRODUCT TESTING AND CERTIFICATION - INTERNATIONAL

A rationale for adoption of a U.S. national accreditation scheme for third party certification agencies may ultimately be found in the need for interaction with foreign certification systems - particularly with the developing system in Europe. It is A.G.A.'s position, however, that the rationale is not yet well developed or compelling. In addition, we are not convinced that the U.S. government needs to be the operator of such an accreditation program. In A.G.A.'s experience, international certification schemes can evolve more effectively via bilateral agreements without the imposition of governmental regulation.

Since 1986, A.G.A. has been engaged in the step-by-step development of operating procedures and confidence-building interchanges with counterpart certification bodies in Japan, Europe, Australia and Canada. We have bilateral agreements in-place with agencies in four nations and other arrangements are pending. In general, these agreements provide for exchanges of personnel, factory inspection services, and quality assurance information en route to future exchanges of product test data and joint issuance of certification marks. Our exchange program with the Canadian Gas Association is the most advanced.

For more than two years, A.G.A. and CGA have been coordinating product test programs so that U.S. and Canadian manufacturers could get one product sample tested at one time, in one location, with both agencies' engineers available at the scene. Both agencies have issued their certification marks and test reports based on this one test program.

As of March 1, 1990, A.G.A. and CGA have agreed to a full exchange of test data for virtually all gas appliances and control equipment destined for sale in the U.S. and Canada. Our mutual customers can elect to have their products tested by either agency for compliance with both U.S. and Canadian standards. The "lead" laboratory will design and coordinate the test program with the "follow" laboratory. The lead laboratory will then conduct all of the tests, prepare the data package and issue the report for both agencies. The follow laboratory will issue its certificates based on the lead laboratory's work without duplicate testing of the same product. Substantial reductions in both certification time and overall certification cost are expected. The agreement also embodies other arrangements for sharing factory inspection assignments.

The major learning from our Canadian activity has been that interchanges of certification services require the build-up of mutual confidence over time. This is not just confidence between the two management groups, but confidence at the operating level where our technicians and engineers meet. This is not just confidence that instruments are correctly calibrated and forms properly dated, but confidence that no tests are waived for arbitrary reasons.

VII. REGISTRATION OF QUALITY SYSTEMS - NATIONAL

The ANSI standards, used by A.G.A. for product certification, have incorporated manufacturing and production tests since the 1970s. These tests were adopted by the gas industry to provide means for third party testing agencies to apply uniform quality control standards to certified gas products. The requirements include provisions for inspection of raw materials and fabricated components. Tests are run by the manufacturer on critical elements of the gas supply train and finished appliances. A.G.A. and other third party certifiers have monitored use of these tests via long-standing factory inspection procedures.

About 4 years ago, A.G.A. started searching for a better set of criteria to use in evaluating and accepting manufacturers' plans for conducting production tests. Fortunately, the ISO 9000 series of standards appeared at about this time bearing international recognition.

We became one of the first U.S. agencies offering to register manufacturers' quality assurance systems that comply with the ISO 9000 standards. On a voluntary and optional basis, our certification customers can request registration. A.G.A. offers a reduction in factory inspection frequency for those customers who operate under an A.G.A. registered quality plan. Our registration program allows A.G.A. to give manufacturers tangible credits for substantial investments in defect prevention systems for making gas products that consistently comply with safety and performance requirements.

VIII. REGISTRATION OF QUALITY SYSTEMS - INTERNATIONAL

The Europeans' global approach to product testing and certification has also seized on use of the ISO 9000 series of quality standards as one of the means that manufacturers may use to achieve conformance with EC directives and EN standards for regulated products - like gas appliances. As a consequence, A.G.A. is negotiating arrangements with foreign certification bodies to achieve mutual recognition of registration programs for manufacturers who want to sell products in both the U.S. and foreign markets.

In this particular area of quality system registration, we suspect that some means of accrediting registration schemes may be needed for both domestic and international purposes. The American Society of Quality Control (ASQC) has already entered this arena and ANSI is studying the same subject.

Once again, since private sector bodies have demonstrated both willingness and forethought in offering registration systems, seeking foreign recognition and implementing accreditation programs, the need for U.S. government intervention or sponsorship appears unnecessary. It may be appropriate for the U.S. government to "recognize" private sector accreditation programs, but it should not be necessary to form a new quasi-governmental body to replace those already formed or forming under private sector initiatives.

IX. CONCLUSION

The U.S. private sector, and the U.S. gas industry in particular, has not been inattentive or idle in recognizing the formation of global markets for manufactured products. A.G.A. and its members, certification customers and standards committees are responding. We have a strategy for harmonizing standards, reducing certification barriers, and installing working arrangements with foreign agencies and their standards/certification systems. We do not see compelling reasons for replacing private sector initiatives with new U.S. government agencies or regulations.

At the same time, A.G.A. is an advocate for real U.S. government participation and cooperation in the forums and activities that are underway to protect and promote U.S. trade. We encourage the U.S. government, and the Department of Commerce in particular, to maintain a leading position in government-to-government negotiations that open doors for private sector initiatives but do not foreclose a role for the private sector in protecting and furthering business interests.

Respectfully submitted,

THE AMERICAN GAS ASSOCIATION

March 22, 1990 By: GHLawrence
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AUG 22 1990

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August 17, 1990

The Honorable Tim Valentine
Chairman, Science, Research and
Technology Subcommittee
Science, Space and Technology
Committee
U.S. House of Representatives
2319 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Valentine:

During the June 26, 1990 hearing of your subcommittee on the Federal role in international testing, certification and quality assurance, you asked ACIL if we could determine the impact that "non-notification" of U.S. laboratories under the EC scheme would have on U.S. laboratories, both in dollars and in lost business.

An exact or even approximate dollar figure is hard estimate, but allow me to offer this analysis, Virtually all U.S. products destined for the European marketplace that have some safety, health, environmental or consumer impact will have to be tested by a European testing laboratory (a "notified body"). These are products that range from the very simple (such as paint) to the very complex (such as computers and peripherals). The point is, is that testing underlies the acceptance of all these products. Testing supports billion dollar industries in the United States. The dollar losses, while nonspecific, are staggering.

As for loss of business to U.S. laboratories, put yourself in the shoes of a U.S. manufacturer who has used XYZ testing laboratory to perform all his testing for the last twenty years on products destined to the EC (not unlike the situation explained by Retlif Testing at the hearing). Under the EC scheme, that manufacturer is now

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being forced to use an EC-based laboratory to test products for that market. That EC-based laboratory is able to do business in the U.S. because we do not discriminate against foreign laboratories. To use the EC terminology, EC laboratories are free to become "notified" in the U.S. Therefore, if you are a U.S. manufacturer and you can test products for both the U.S. and EC markets by using one laboratory, and that laboratory is located in the EC because they will not "notify" U.S. laboratories, you will use the EC laboratory. The U.S. laboratory is completely eliminated from the business. If the EC scheme is left unchanged, there will be few U.S. laboratories remaining.

It is not in the United States' best interest to allow EC laboratories to determine what U.S. products are safe, healthy and environmentally sound. U.S. laboratories wishing to test products for export to the EC should be treated on an equal basis with EC laboratories, just as EC laboratories are treated in the United States. This means non-discriminatory national treatment.

Once again, thank you for the opportunity to share our views on this subject with the subcommittee. We will be happy to answer any questions that you may have and cooperate with your staff to the fullest.

Sincerely,

Herbert Wilgis
Vice-Chairman
ACIL Government Affairs Committee

Milton M. Bush, Esq., *Director of Public Affairs*

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September 10, 1990

The Honorable Tim Valentine
Chairman, Subcommittee on Science,
 Research and Technology
Committee on Science, Space and
 Technology
Rayburn House Office Building, Room 2321
Washington, D.C. 20515

Dear Congressman Valentine:

This letter is to serve as a supplement to the oral testimony of the American Council of Independent Laboratories (ACIL) at the June 26, 1990 hearing of your subcommittee on the Federal role in international testing, certification and quality assurance. I would like to request that it be entered in the hearing record.

My role at the June 26th hearing was as counsel to Mr. Herbert Wilgis, who testified on behalf of ACIL. In that role, I fully intended to supplement ACIL's views on the hearing subject, but in particular, the role of the American National Standards Institute (ANSI), as a representative of the private sector, in international testing, certification and quality assurance issues. It was only due to the bifurcated nature of the hearing (due to the historic speech of Mr. Mandela to a joint session of Congress) that I was unable to relay these thoughts orally.

First and foremost, a great deal of credit should be given to ANSI for the leadership role that they have taken in regard to testing, certification and quality assurance issues relating to EC 1992. Their organization, coordination and implementation of three (3) very successful private sector delegations to the EC to meet with private and public sector officials on emerging EC issues has been of tremendous benefit, not only to ACIL, but we believe, to the United States as a whole. ACIL has been invited and has been a participant in all three (3) missions. I have attended two personally.

Second, it's my impression that the Subcommittee may be coming to the realization that a focal point for testing and certification issues in the U.S. is sorely needed due to the fragmented nature of our system. ACIL feels that a successful strategy should be joint public/private cooperation. Such cooperation should maximize the strengths and minimize the weaknesses of each sector.

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This view is ACIL's. There are many other views, however, which are derived from international considerations. Congress or the Executive Branch cannot be expected to assimilate these views (much of which are technical in nature) in the time necessary to respond to rapidly moving international developments so as to develop sound public policy. This is why ACIL has advocated the creation of a Congressional Commission. Such a body would be advisory and could assist the Congress in evaluating what is ultimately in the best interest of the United States.

ACIL fully expects ANSI to play a role in the solutions available to these current international challenges, a role that can assist the U.S. government in developing public policy.

Sincerely,

Milton M. Bush, Esq.
Director of Public Affairs

CEN/CENELEC
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March 1989

CREATION OF A EUROPEAN FRAMEWORK FOR TESTING AND CERTIFICATION

An introduction to CEN/CENELEC's Proposal

Background

An aim of the Single European Market subscribed to by both the EC and EFTA is to abolish technical barriers to trade. Major progress is being made in this through the harmonization of standards and technical specifications. Particular incentives to aid this are the European Community's 7 May 1985 New Approach to technical harmonization and standards and current Community policies in the field of public purchasing. These positive steps can, however, be undercut by the mechanisms in place for the establishment and demonstration of conformity. The act of agreeing a common standard will not remove barriers to trade if practical requirements for the demonstration of conformity continue to differ from country to country.

Both the Commission of the European Communities and the EFTA Secretariat support policies to overcome such barriers by augmenting rather than diminishing quality. In "A Policy Statement of the Commission on Technical Specifications, Testing and Certification : The Global Approach" (Certif 88/10) The Commission advocates a Single Market based on confidence in quality procedures operating throughout the European economic space. To achieve this confidence, common doctrines must be developed and accepted.

Any requirement for testing and certification normally depends on the partners in trade (producers, purchasers, users, consumers etc...). If the purchaser feels his own judgment to be insufficient and therefore prefers to refer to the expertise of specialists, testing and certification, as detailed below, is one of the possible options.

Testing and certification operate at present in European countries in three main spheres :

1. The establishment of conformity to specifications is a strictly private, bilateral matter between the client and his supplier. The client only requires a declaration of conformity made by the supplier, and carries out verification himself on receipt of the products.

   In this situation there is, strictly speaking, no problem over 'mutual recognition' between different countries. By definition, responsibility for the declaration of conformity of the manufacturer lies solely with the latter, and is valid in all countries - provided the customer has confidence in this procedure.

2. At the other extreme, there are product areas where States have introduced the requirement of measures to indicate conformity to protect interests of their citizens, such as security, health and safety, environmental protection etc.

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Harmonization of such requirements is the province of governments and community institutions, and is achieved through legislation and legal procedures.

3. Between these two spheres, there exists a third sphere which comprises areas where conformity has been agreed upon voluntarily between economic partners to regulate the exchange of goods. These procedures tend to have been developed through consensus in each country, whereby this consensus reflects the habits of the market. The mutual recognition of systems of one country by another country is therefore not easily organised. Unlike the statutory area, it is not subject to governmental control.

The same product, complying with the same specification, may be subject to combinations of the above, whereby voluntary requirements are added over and above mandatory ones in many areas.

A European Framework for Testing and Certification

It is for this third sphere that a framework is necessary to assist users of certification (purchasers, insurers, etc.) to have a basis for confidence in the process of evaluation by any party in Europe. Mutual recognition will be achieved the day when these economic operators will have the confidence to refer in their contracts, without discrimination, to a process of evaluation of conformity largely operated in the country of origin, but transparently in conformity with the procedures in use in their own countries.

The following conditions are necessary to achieve this objective :

1 the qualifications of the bodies that carry out the procedures must be generally acceptable;

2 the differences, if any, in the systems operating in the different countries may not be so significant as to prevent in practice any cooperation;

3 the economic partners who have been behind the consensus at the national level, thereby shaping the national systems, must contribute similarly to the European consensus so as to ensure that the European system reflects their real needs.

The recognition of the essential role of consensus by the European Commission and EFTA authorities led to the organisation of the Symposium in June 1988 to consult the interested parties as to their requirements. This Symposium resulted in an invitation to CEN/CENELEC, as bodies dedicated to obtaining consensus at the European level in the field of standardisation - standards providing a major basis for testing and certification, themselves being a source for standards - to make proposals for the organisation of testing and certification in Europe.

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The CEN/CENELEC Proposal

The Commission invited CEN/CENELEC to develop, in close cooperation with the former, a sector based infrastructure for certification and testing. In this context CEN/CENELEC should make the necessary contacts :

- with the various interested parties to determine the priorities of sectors, as well as

- with the various international groupings that would be able to provide specialised support in the fields of testing, calibration, certification and quality assurance (letter from the Commission of 29 July 1988).

CEN/CENELEC therefore propose that the specific organization to be set up in Europe, in order to fulfil the above-mentioned 3 conditions be created according to the following principles :

- The recognition of the qualification of test laboratories and certification bodies will be carried out in principle at the national level, according to the common practice of each country, but following a harmonized doctrine, and in a transparent fashion.

- The cooperation between test laboratories, certification bodies, or both, will be achieved in the framework of cooperation agreements, called within the CEN/CENELEC proposal "arrangements", in accordance with ISO/IEC vocabulary. These arrangements are jointly managed by the bodies involved and they provide in particular for practical mutual recognition of test results, for delivery of harmonised certificates, etc.

- The formation of consensus of the economic partners on the actions taken towards mutual recognition, which is essential to actually make this mutual recognition process sucessful on the market place, has been carefully considered by CEN/CENELEC, as it is the most complex part of the project.

It is self-evident that the envisaged structure must take into account in a proper way and ensure the participation of :

- national interests
- interests of parties concerned
- knowledge and experience in specific sectors

But, to combine all this into one single body would result in an extremely large group which would not be in a position to come to conclusions in an efficient manner; using the descriptions in the earlier consultative document of the CEC Certif 88/1, representation would comprise at least 8 different groups of interest for each individual country :

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- accreditation bodies
- certification bodies
- testing laboratories
- standards makers
- manufacturers
- trade unions
- consumers
- professional groups

Since the European framework is expected to cover the wide variety of at least all industrial activities (goods and services), and could possibly even go beyond the industrial world, it is clear that in a majority of the member countries some group of interest could not be represented by a single person but would express the need to send several persons. This would apply for example to the manufacturing activities in particular industrial fields, to different groups of users or to different governmental services. Thus, the total number of people participating in one single governing body would be more than eight per country to be multiplied by the number of the EC and EFTA countries.

In order to avoid this difficulty, CEN/CENELEC proposes that most of the work be undertaken in the Sector Committees which should consist of national delegations. The relevant European discussions and activities must be well prepared, which could best be done by requesting a national organization to assemble at that national level representatives from all parties concerned: if this is done sectorwise, there should be no problem to find experts having the necessary knowledge for the whole sector (without being experts in other sectors). In this way the interests of the parties would lead to a national view covering therefore the totality of national interests. The national delegations in the Sector Committees would be bound to represent these views and not only those of a certification body or of manufacturers.

In such a context, the horizontal structure (ETJC) should deal with questions which are not specific to a single sector but would constitute the general basis for the work in several or in all sectors. It is evident therefore that sound conclusions could only be reached (and be followed) by taking into account the particularities of all the sectors concerned. This requires that ETJC should primarily be composed of representatives from the Sector Committees.

The above considerations have led to the CEN/CENELEC proposal as the most reasonable solution for the purpose of this exercise. Again, it should be stressed that this proposal is valid with the following understanding :

- the national delegations in Sector Committees represent all parties concerned within their respective countries;

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- the delegates from sector committees represent within ETSC the views of the sector and not those of a specific country or party.

Sundry Proposals

Beyond the above proposal, CEN/CENELEC offers the following to foster its implementation :

1 administrative support (where necessary) for the coordination of mutual recognition arrangements

2 support (where necessary) for the achievement of the required broad consensus behind arrangements

3 coherence, transparency and momentum.

The link between the independent framework for the organisation of testing and certification at the European level and standardisation within CEN/CENELEC will be naturally strengthened as European standards progressively provide the necessary technical tools in harmonized form. The European standards which contribute to the support of the structure are the EN 29000 series of quality system assessment standards and the seven ENs providing criteria for certification bodies and testing laboratories and their accreditation (which are due to be adopted as the EN 45000 series) and the relevant harmonized product standards.

The attached file consists of documents which detail the CEN/CENELEC Proposal and provide information on relevant background developments.

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March 1989

MEMORANDUM ON

THE CREATION OF A EUROPEAN FRAMEWORK FOR TESTING AND CERTIFICATION

PROPOSAL FROM CEN/CENELEC

CONSIDERATIONS

a) Considering the need among other tasks for the completion of the Internal Market and effective economic development in western Europe to reduce costs relating to testing and certification and improve competitiveness whilst maintaining the objective of ensuring high levels of quality and safety :

b) Considering that the achievement of these aims requires the willing cooperation of all the technical bodies and other parties involved ;

c) Considering that, in order to gain the maximum economic impact, testing and certification in all appropriate forms must be developed in an harmonious fashion and promoted at European level, to provide the market with adequate assurance of the quality and reliability of the procedures involved ;

d) Considering that the CEC consultation document "Certif. 88/1" and the conclusions of the CEC "Symposium on organizing certification and testing for Europe" of 21 - 23 June 1988 invited CEN/CENELEC to develop, in collaboration with the European Economic Commission and the EFTA Secretariat, a testing and certification infrastructure and to make the necessary contacts with interested parties to determine priorities for Sectors, as well as with the different international entities that could constitute specialized support in the specific fields of testing, calibration, certification and quality assurance.

Considering the CEC policy statement on a global approach on technical specifications testing and certification in document "Certif. 88/10". Considering that the EFTA Convention supports the same ideas;

e) Considering that, in order to maintain the coherence of European Standardization, all standardization related matters must remain under the full responsibility of the recognized standardization bodies;

f) Considering that the European policy should have due regard to existing arrangements between testing laboratories and certification bodies which should not be hampered by the introdution of the present proposal.

CEN/CENELEC make the following proposal :

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1 - SCOPE

In order to overcome the barriers to trade caused by requirements for national test reports, certificates or marks of conformity, it is necessary both to develop the use of manufacturers' declarations and to provide a framework for the development of mutual recognition of such test reports, certificates or marks of conformity on the basis of full confidence achieved through the participation of the various interested parties.

CEN/CENELEC offers such a new framework dedicated to coordination, in all areas relevant to the functioning of the internal market of the EEC and EFTA countries, of activities relating to conformity with defined technical requirements of products, processes and services (including conformity with requirements of quality systems and assessment of competence).

2 - FRAMEWORK

This framework will consist of :

a) Sector European Certification Committees (referred to below as Sector Committees) which will implement the above mentioned coordination within their areas of competence. These Sector Committees may be either product oriented (e.g. electrotechnical, information technology,...) or discipline oriented (e.g. calibration, testing, certification, quality systems,...).

b) The European Testing and Certification Coordination Council "ETCC" which will provide for overall coordination and promotion of all measures aimed at avoiding repetition of testing and certification. In this context ETCC may seek advice from relevant Sector Committees or set up advisory groups.

3 - SECTOR EUROPEAN CERTIFICATION COMMITTEES

Sector Committees will not themselves operate any testing or certification arrangements or European testing or certification systems. These will be managed through cooperation between the participating testing and certification bodies.

3.1 - Role of the Sector Committees

a) Design and maintain rules in its area of competence for recognition arrangements and for European testing and certification systems. Consultations at the national level carried out through public enquiries by the relevant CEN/CENELEC member according to the CEN/CENELEC common procedures will ensure that these rules reflect consensus among the parties concerned.

b) Evaluate the conformity of proposed testing and certification arrangements to the rules and to the criteria set out by ET3C. This process includes the procedures, carried out at the national level, to evaluate compliance with the rules by the testing laboratories and the certification bodies proposing to participate in a recognition arrangement or a European system.

c) Promote the recognition arrangements and European systems within their area of competence.

d) Foster new initiatives for further improvement and enlargement of the recognition arrangements and the European systems.

e) Review regularly the compliance of recognition arrangements and European systems with the rules.

f) Organize on a permanent basis appropriate access to information about the recognition arrangements, the European systems and the technical bodies that participate within them.

g) Provide an appeal procedure.

h) Maintain dialogue with similar organizations in other countries and regions, with a view to reaching an appropriate state of coordination at the international level.

i) Appoint delegates to ET3C.

3.2 - Composition

Each Sector Committee will be composed of national delegations. In order to ensure the representation of the various interests the national delegations will be the result of consultations at national level. To achieve proper consensus and co-ordination of the standardization testing and certification activities, these consultations will be organized by the relevant CEN/CENELEC member or in close co-ordination with it.

For the sake of good administration, the national representation to each Sector Committee will be formally notified to the ET3C secretariat by the CEN/CENELEC member.

As appropriate, Sector Committees may invite individuals or organizations to participate in meetings as observers.

3.3 - Rules of Procedure

All Sector Committees will establish and maintain their rules of procedure and elect their chairpersons.

3.4 - Administration and Finance

CEN/CENELEC offers to provide administrative support to operate Sector Committee secretariats. In this case their costs will be covered by the relevant Sector Committee budget through the general budgets of CEN/CENELEC. If the administrative support for a Sector Committee is not provided by CEN/CENELEC, the secretariat shall always be a non-profit independent entity.

Each Sector Committee will make its own financial provisions.

4 - THE EUROPEAN TESTING AND CERTIFICATION COORDINATION COUNCIL (ET3C)

ET3C will not itself operate any testing or certification arrangements or European testing and certification systems.

4.1 - Status of ET3C

ET3C will be an autonomous body within the framework set up by CEN/CENELEC.

ET3C will be invited to be represented at the General Assemblies of CEN and CENELEC to ensure proper co-ordination between its activities and standardization.

4.2 - Role of ET3C

ET3C

a) will provide coordination between the Sector Committees.

b) will maintain the basic principles involved in the establishment and operation of the framework constituted by this memorandum and their general acceptance, and will monitor their application on a continuing basis within the Sector Committees.

c) will cooperate with the CEC and the EFTA Secretariat and other major interests.

d) will promote further implementation of this memorandum where need arises.

4.3 - Composition

ET3C will be composed of members representing the Sector Committees. Each Sector Committee may appoint 1 representative and 1 alternate.
Each EEC and EFTA country with membership in CEN/CENELEC may send one observer who will be formally notified to the ET3C secretariat by the CEN/CENELEC member.

The CEC and the EFTA Secretariat as well as the CEN and CENELEC Central Secretariats have the permanent right to send representatives to ET3C meetings as observers.

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UNICE (Union des Confédérations de l'Industrie et des Employeurs d'Europe), ETUC (European Trade Union Confederation) and CCC (Comité consultatif des Consommateurs de la Communauté Européenne) may each nominate 1 observer.

ET3C may invite experts to attend meetings for discussion of specific agenda items (e.g. in view of the establishment of new Sector Committees).

4.4 - Rules of Procedure

ET3C will establish and maintain its rules of procedure and elect its chairperson.

4.5 - Administration and Finance

The cost of the ET3C administration will be covered by its own budget through the general budgets of CEN and CENELEC:

> Within the limits of the ET3C budget, CEN/CENELEC will undertake, on behalf of and at the expense of ET3C, the agreed administrative and secretarial support for the central acitivities of ET3C. This is to include, as required by ET3C, the provision for office space, general services and the employment of ET3C permanent staff recruited in agreement between the parties.

CEN/CENELEC will operate a specific accounting of the expenses and income of ET3C and will provide CEN AG and CENELEC AG a report of these accounts.

STATEMENT

to

U.S. House of Representatives Subcommittee on
Science, Research and Technology

on

Standards, quality systems, inspection, test and certification.

by

HARVEY E. SCHOCK, JR,

June 22, 1990

PURPOSE: This statement offers information for consideration in attempting to resolve various legislative problems relating to standards, quality systems, inspection, test and certification.

Product Assurances Consulting
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Presenter Qualifications:

The originator of this statement is a consultant. Background includes Engineering degree from Cornell University and 30 years with the RCA Corporation, with last 14 years as the Corporate Worldwide Administrator for Product Assurance. Present activities include active consulting in various national and international areas on the subject topics.

Statement:

It is proposed the present alleged problems in standards, quality systems, inspection, test and certification be solved by the use in continuing legislation of the following set of words:

> The Department is directed to work with other federal activities and with voluntary standards developing activities in the United States, and outside the country as appropriate, to identify and use opportunities for improving requirements and criteria for standards, quality systems, inspection, testing, accreditation and certification. Where there are found to be alleged problems or opportunities for change, and following study of the standards and other activities, the Department is requested to evaluate resulting new or changed standards and implement as appropriate in accordance with established objectives and activities of the Department. The Department shall work with other appropriate federal departments for resolution and action. This complete cycle of review, recommendations, and action shall be accomplished within one year of this legislation and a report on accomplishments shall be provided by the Department to the Congress.

This would eliminate the need for extensive special commissions to study alleged problems, as the work would be done within the existing government structure through OMB Circular A-119 with voluntary and public participation.

Use of the above recommended wording also avoids attempting to prescribe specific detailed government approaches and controls in these continually changing areas, requirements and practices of standards, quality systems, inspection, test, accreditation and certification.

Supporting information is on following four pages.

Thus the actions would consist of:

1- Utilize guidance provided in these Hearings to develop apecific words which can be inserted in legislation when and only when there is evidence of problems dealing with Standards, Inspection, Test and Certification.

2- Prescribe action shall be taken by presently legislated federal government activities to utilize voluntary standards development capabilities in the United States, and related other suitable regional and international bodies, to identify problems, opportunities and solutions suitable for implementation through existing legislated activities. Note: Where this approach is used it may be necessary to appropriate funds for a specific identified problem or opportunity if beyond the scope of existing legislated activities.

3- Prescribe action should be taken by presently legislated federal government activities to utilize United States government resources, regulatory compliance and enforcement capabilities to identify and enforce appropriate controls for problems, opportunities and solutions suitable for implementation through existing legislated activities.

4- Where existing federal legislated activities determine they are not capable of handling the situation, within their government department or agency activities responsible for the alleged situation, it shall be responsible of that department or agency to explore and develop solutions to the problems and opportunities and to make necessary specific recommendations for action in its area. When this is done or where a department or agency determines it is not capable of handling a specific situation then it shall make specific recommendations to the Congress for changes to existing legislation or the creation of new legislation.

5- The government department or agency responsible for the above actions shall utilize as appropriate the services of other federal government activities, state and local government, industry and the public.

6- An example of this approach is to be found in Section 110(c) of the Surface Transportation Assistance Act of 1982. This Section 110(c), and its specific resulting actions, resulted in U.S. Department of Transportation, Federal Highway Administration, review to improve the quality and reliability of the design and construction of highways and bridges by working with the U.S. voluntary standards system in the U.S. The review included identifying problems and opportunities for improvements in Design, Legal, Bidding, Contracting, Standards, Construction, Inspection, Test, Accreditation and Certification. The action included FHWA preparing ten papers covering these areas which were distributed to the public. A two day workshop was then held at DoC NIST reviewing and developing recommendations, with recommendations received from the public. This was accomplished in one year resulting in a report to Congress on recommendations and citing actions and changes it had been able to implement within the existing legislated structure without requiring additional laws or funding.

7- For Standards development and use, this would be consistent with OMB Circular A-119. For Quality Systems, Inspection, Test, Accreditation, and Certification this would be consistent with existing practices. Where conflicts are discovered the responsible Department would be for determining resolution.

DISCUSSION:

Just as there is criticality in design of a process, product or service for production and sale, so there is criticality in design, integration and operation of a standards system and related Inspection, Test and Certification.

It is necessary to consider the various activities involved in designing and producing as well as in the normal conducting of ongoing and final accreditation and certification. This requires considering the criticality of design for a process, product or service with careful review of the following aspects:

Integrated design for materials and inputs of items entering the system.

Integrated design for developing controls of the items and variability for suitability in production.

Integrated design for operation and controls of the process, product or service.

Integrated design for assurance and controls to be applied to evaluate an item as it flows through the process.

Integrated design of controls for actual operation of the production.

Integrated design for requirements and activities applied in accreditation and certification of the design and production capability for each element of production.

Integrated design for requirements and activities applied in accreditation and certification of production capability for each element and for the total production system.

Integrated control of activities identified to be applied in conducting actual accreditation and certification.

Integrated control of the system to be applied to evaluate and control activities of actual accreditation and certification.

Integrated control of activities to be applied to evaluate and control the decisions and results of actual accreditation and certification.

Integrated control of activities to be applied for possible appeals to decisions cn actual accreditation and certification.

All of the above steps must be integrated into Standards and the subsequent operations of Inspection, Test and Certification. This includes evaluating related quality systems of: the producers of the materials for inputs; the process, product or service for production; and the operation of accreditation and certification.

To write legislation to cover all of the above is an almost impossible task for generic or general scope as well as for specific areas.

A proposed harmonized European implementation of Certification is covered in the European Commission, Global Approach to Certification and Testing, Quality measures for industrial products, COM(89) 209 final - SYN 208, of 19 October 1989. This sets out to remove technical barriers to products on the basis of a "new strategy" which combines harmonization with mutual recognition of national regulations and standards. This includes a policy for the assessment of conformity on an equal footing for all the Community Member States.

The system notes the requirement "to examine and approve a system of quality management (using quality assurance techniques) and to perform periodic checks in the plants of the certified firms." Unfortunately one of the objectives is to enable a supplier "to be also capable of becoming a major factor in the promotion of industrial quality and, hence, of the competitiveness of European firms, both in the internal market and beyond." This implies promotional use which could possibly compromise the effectiveness of assessing and managing the meaningfulness of quality management systems.

The system uses a growing set of standards for which there is not a complete set of parallel U.S. standards or even ISO/IEC Guides. The European standards include:

CEN/CENELEC EN 45000 Series Standards Published September 1989:

EN45001	General criteria for the operation of testing laboratories
EN45002	General criteria for the assessment of testing laboratories
EN45003	General criteria for laboratory accreditation bodies
EN45011	General criteria for certification bodies operating product certification
EN45012	General criteria for certification bodies operating Quality Systems certification
EN45013	General criteria for certification bodies operating certification of personnel
EN45014	General criteria for declaration of conformity.

In addition:

EN45019	Guidance on specific aspects of testing and certification. (mutual recognition proposal). (EN 45019 Balloted but Rejected in 1990 European voting.)

The system also notes: "the EN45000 series of standards is incomplete since it does not yet cover all conformity assessment activities. It will be necessary, in particular, to establish criteria for the inspection bodies and for the bodies responsible for accrediting the certification and inspection bodies. Standardization mandates to this end will be issued shortly to CEN/CENELEC."

This was as of October 1989 and, despite new channels as of June 1990, it has been impossible to obtain any indication of planned CEN/CENELEC specific work projects to permit awareness by and possible contribution from the U.S. Thus it can only be assumed that all standards projects underway in ISO, IEC, and CASCO are now candidates for Community regulatory use through CEN/CENELEC.

A detailed study of the European system for certification shows references to CEN/CENELEC EN 29000 and EN 45000 series standards. There are also additions, deletions and changes to cause problems. Further the EEC Certification Modules of A through H do not necessarily represent the final approaches for regulatory application. The Modules are:

A - EC DECLARATION OF CONFORMITY
B - EC TYPE EXAMINATION
C - EC DECLARATION OF CONFORMITY TO TYPE
D - EC DECLARATION OF CONFORMITY TO TYPE
(Production Quality Assurance)
E - EC DECLARATION OF CONFORMITY
(Product Quality Assurance)
F - EC VERIFICATION
G - EC UNIT VERIFICATION
H - EC DECLARATION OF CONFORMITY
(Full Quality Assurance).

These EEC Modules are similar to ISO Book "Certification, Principles and Practices", 1980, which presents Classes of tests or evaluations used to determine certification of a process, product or service. The ISO Book is presently under revision with draft expected by the end of 1990.

For the United States there is generally accepted use by the federal government and industry of TWO generic national standards for Certification:

ANSI Z34.1-1987 American National Standard for Certification - Third-Party Certification Program, and

ANSI Z34.2-1987 American National Standard for Certification - Self-Certification by Producer or Supplier.

Thus rather than the complicated EEC Modules of A through H, it is proposed for the United States to continue to apply these two Z34 standards through a simplified three element structure for a selected Certification System.

A- The actual approach or Certification TRACK to be selected would depend on the production status of the items or areas to be accredited or certified:
1- For one of a kind items.
2- For untooled items.
3- For tooled items.

The use of "tooled" and "untooled" relates to the system and controls used for the actual design and production of the item being accredited or certified. The "item" may be a process, a product, or a service. The selection of the Track would be determined by the producer and the accreditor or certifier. The approach could also be determined by a specific standard for an identified process, product or service or by requirements in a regulation.

B- The choice from one or more of three Certification METHODS to be used:
1- Type Test - original qualification prior to or repeat during production.
2- Pre-production - using actual tools at start of actual production.
3- Production - for items in continuing production.

C- And there would be three Certification TIMING approaches to implementing:
1- Preliminary to applying for formal accreditation of certification.
2- Performing review for actual accreditation or certification.
3- Investigation or continuance for accreditation or certification.

Thus for a typical accreditation or certification program the elements could consist of an approach using a combination of Track A3, Method B3. and Timing C2. This simplifies EEC Modules A - H.

Note: This approach changes the European term of "Module" to a U.S. term of "System". The word "module" is reserved in the U.S. to better describe the elements of design and control used for quality systems, accreditation or certification. The use of "modules" permits developing simplified requirements and criteria for producers, accreditors and certifiers to reduce the complexity of preparing for, assessing and implementing systems for quality, accreditation or certification.

Standards for processes, products, or services and regulations would adopt the above preferred or required steps by reference. Requirements and criteria would be identified and standardized for modules to be used by producers and applied in accreditation or certification. Similar modules would be used by assessors, surveyors or auditors in evaluating quality systems, inspection, test, and certification activities of the producers. The result would be elimination of unnecessary confusion and multiple requirements. This would combine requirements in common wording. Simplification would be achieved.

In the above discussion reference is made to accreditation and to certification. For certification ANSI Z34 standards would apply. For accreditation, as for testing laboratories, the standards would be ASTM E548, ASTM E994, and associated ASTM standards. For quality systems use would continue with ISO 9000, EN 45000 and equivalent ANSI/ASQC Q90 series, with 9001 covering quality assurance in design, development, production, installation, and servicing; 9002 covering quality assurance in production and installation; and 9003 covering quality assurance in only final inspection and test.

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END... RITCGVT3.STD 900622